(1) Supreme Court, U.S.
FILED

No. 01-01 660 OCT 16 2001

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In The

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC.,
and
APOTEX, INC., and BERNARD C. SHERMAN,
and
GENEVA PHARMACEUTICALS, INC.,
and
INTERPHARM, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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October 16, 2001

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140 pp

QUESTIONS PRESENTED

1. Did the Court of Appeals err in invalidating Petitioner's basic patent on the antidepressant drug Prozac on the ground that the 1974 discovery claimed by the patent was "obvious" when compared to a second patented discovery that was not even made until 1983, years after the 1974 discovery was first publicly disclosed as "prior art"?

2. Did the Court of Appeals err in ruling that Petitioner was not entitled, despite the plain language of 35 U.S.C. § 253 and uniform precedents applying it, to preserve the validity of its basic Prozac patent by "disclaiming" the final seven months of its patent term held by the court to be an "unjustified timewise extension" of patent exclusivity?

PARTIES AND CORPORATE DISCLOSURE

There are no named parties other than those stated in the caption. Eli Lilly and Company has no parent company and no subsidiaries or affiliates that have issued shares to the public.

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PETITION FOR A WRIT OF CERTIORARI

Eli Lilly and Company ("Lilly" or "Petitioner") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals is reported at 251 F.3d 955 (Fed. Cir. 2001) and is reprinted in the appendix hereto ("App.") at 1a. The court of appeals order denying rehearing and rehearing *en banc* is not reported and is reprinted at App. 95a. The initial opinion of the court of appeals was reported at 222 F.3d 973 (Fed. Cir. 2000) and is reprinted at App. 57a. This initial opinion was vacated by the *en banc* court of appeals in an unreported order reprinted at App. 37a. The unpublished opinion of the district court is reprinted at App. 86a.

JURISDICTION

Judgment of the court of appeals was entered on May 30, 2001, and the order denying rehearing and rehearing *en banc* was entered on July 18, 2001. This Court has jurisdiction under 28 U.S.C. § 1254.

PERTINENT STATUTORY PROVISIONS

Relevant provisions of the patent statute are codified at 35 U.S.C. §§ 100(b), 101, 102, 103, and 253, and are reprinted at App. 101a. Of particular relevance to the first question presented is Section 103(a), which in pertinent part provides:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Section 253 is especially relevant to the second question presented. In pertinent part, it provides that "any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted."

STATEMENT OF THE CASE

A. Introduction

In the decision below, a panel of the Federal Circuit invalidated Lilly's basic patent for the revolutionary antidepressant drug Prozac, prematurely ending Lilly's marketing exclusivity two and a half years (and at least $4 billion in sales) before the expiration of the patent's statutory term in December 2003. No less startling than the result of the decision was the reasoning that yielded it: the panel determined that the 1974 discovery claimed in the basic Prozac patent was "obvious" when compared to a discovery that was not even made until 1983.

At the heart of the case are two patents. One of these patents (the "Molloy" patent) claims Lilly's basic discovery that Prozac's active ingredient, fluoxetine hydrochloride, is especially effective at inhibiting uptake of serotonin in the brain. This discovery, first publicly disclosed by Lilly in the 1970s, led to a host of follow-on inventions by Lilly and by others. The second patent (the "Stark" patent) claims Lilly's 1983 discovery of a "new use" for Prozac – that Prozac, in appropriate doses, treats anxiety in humans.

The panel held that Lilly's Molloy patent ran afoul of the doctrine of "obviousness-type double patenting," a judge-made rule designed to prevent one patentee from obtaining two or more separately valid patents for the same invention or an obvious variation of the same invention. The "double patenting" doctrine exists to prevent such patents from having separate patent terms that

might otherwise create "an extension of the patent right beyond the statutory time limit." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

Central to the panel's decision was the fact that the basic Molloy patent issued seven months later than the Stark "new-use" patent and, thus, has a statutory term that will expire seven months after the statutory term for the Stark patent will expire. Hence, according to the panel, the effect of owning two patents rather than one patent is to provide Lilly with an extended period of exclusivity seven months longer than it would have been if Lilly had been issued only the Stark patent. The court believed this extra seven months constituted an "unjustified timewise extension" of Lilly's period of exclusivity. The crux of this determination was that the basic Molloy invention was "obvious" in view of the Stark new-use invention.

The problem with the panel's ruling is that it directly contradicts the *statutory* nonobviousness test for separate patentability. 35 U.S.C. § 103. Section 103 of the patent statute specifically conditions patentability for every invention on the requirement that the invention be nonobvious when compared to the "prior art" respecting that invention – that is, the state of knowledge existing "at the time the invention was made." *Id.* But instead of inquiring, as both the statute and commonsense dictate, whether the Molloy invention was nonobvious in light of *previously discovered* inventions in its "prior art," the panel asked the totally illogical question whether the Molloy invention was nonobvious in light of a *later-discovered*, follow-on invention derived directly from the Molloy invention – in effect, *the subsequent art.*

Under the statute, when an inventor shows that he has made a follow-on discovery that is a "nonobvious" innovation in view of the "prior art," including his own earlier

discoveries, he is entitled to a separate patent on his follow-on invention. In other words, if a later-discovered invention is nonobvious in view of an earlier-discovered "prior art" invention, then the two inventions are "patentably distinct" from one another, permitting a separate patent to issue for the later discovery. If the inventions are not "patentably distinct" in this manner, only one patent may validly issue. In short, then, whenever Section 103 applies to assess whether an invention is nonobvious over an earlier "prior art" invention, it necessarily disposes, once and for all, of the issue of "double patenting" – *i.e.*, two patents issuing for the same or obvious variations of the same invention – between those two patents. Indeed, uniform legal precedent stretching back more than a century confirms that if this nonobviousness test applies to two inventions and is satisfied, the statute dictates that two separate patents must issue, and that no "double patenting" can exist.

In accord with this straightforward statutory scheme, the Patent and Trademark Office ("PTO") specifically determined that the new use described for Prozac in the Stark patent was nonobvious in light of the prior art, including the earlier-discovered basic invention claimed in the Molloy patent, and the PTO therefore issued the Stark new-use patent. Because the Stark new-use invention was nonobvious in light of the Molloy "prior art" invention, the patent statute clearly and incontrovertibly dictated that the two inventions cannot constitute double patenting, and that, because *both* inventions were nonobvious when compared to their respective prior art, two valid patents should issue.

The panel, by contrast, did not ask whether Lilly's later-discovered new-use invention (Stark) was obvious in light of its basic invention (Malloy), but instead asked *whether Lilly's earlier-discovered basic invention was obvious*

in light of its later-discovered new-use invention. But this question, whether an invention was obvious in light of another invention that did not yet exist, is akin to asking whether the parent was born after the child.

A basic "prior art" invention cannot be "nonobvious" in view of a later-discovered new-use invention. A new-use invention that builds upon the innovations claimed in the earlier-discovered basic patent will inevitably embody those earlier-discovered innovations, so that, if the two discoveries are looked at in reverse order of their discovery, the basic invention will *necessarily* be "obvious" in light of the new use. In other words, the court applied a judge-made test for separate patentability that literally *reverses* the statutory test, and in so doing doomed Lilly's basic Molloy patent to fail.

The Federal Circuit's error is rooted in the fact that it focused not on the order in which the two *inventions were discovered* but rather on the order in which the resulting *patents issued*. As noted, Lilly's basic Molloy patent issued seven months after the Stark new-use patent, and therefore was due to expire seven months later – in December of 2003. But the order of patent issuance has no relevance to the fundamental precept of patent law that is at stake in this case: two inventions are each separately patentable if the later-discovered invention is nonobvious in light of the earlier "prior art" invention. This statutory test is wholly indifferent to the dates on which the patents on those two inventions issue. And where this statutory test is satisfied and the statute dictates that two patents may issue, the judge-made doctrine of double patenting does not and cannot apply to produce a different result. Thus, the decision below overturned a result mandated by the patent statute, and the profound ramifications of the Federal Circuit's error amply warrant this Court's review.

But the Federal Circuit did not stop there. Even if the decision below were somehow correct, and Lilly's basic Molloy invention was properly declared obvious in light of Lilly's subsequent new-use invention, it is well-established that Lilly is entitled to preserve the validity of its patent by simply "disclaiming" the seven months of "unjustified" extension of patent protection contained in the term of the basic patent, from May 2003 to December 2003. Not only is this result compelled by logic – these seven months, after all, caused the court to reach its result in the first place – it is also unambiguously guaranteed by statute and decades of uniform precedent. *See* 35 U.S.C. § 253.

Inexplicably, however, the Federal Circuit preemptively ruled that Lilly was not entitled to avail itself of the well-settled remedy of disclaiming the excess term of the later-expiring patent. Instead, the court ruled that Lilly must lose the *entire* protection on its basic Prozac patent. This was the Federal Circuit's second major legal error warranting review by this Court.

B. The Subject Matter of the Dispute

Both of the patents at issue in this case issued in 1986, and their 17-year terms are therefore due to expire in 2003. Lilly first began to sell Prozac in the United States in 1988, and at the time of the Federal Circuit decision, Lilly's Prozac sales exceeded two billion dollars per year. Respondents and other generic drug manufacturers have sought to market generic versions of Prozac before Lilly's patents expire.

Although widely known as the most prescribed antidepressant drug in the world, subsequent "new use" discoveries have shown that Prozac can also be effective in treating other disorders, including anxiety, obsessive compulsive disorder, and bulimia. It is Lilly's patent on

the discovery of Prozac's "new use" in treating anxiety that was relied upon by the Federal Circuit to invalidate Lilly's basic Molloy patent.

C. Lilly's Prozac Patents

In 1974 Lilly filed a patent application setting forth a number of innovative discoveries, all of which related to its development of what would later become Prozac. This application became the subject of complex and lengthy proceedings before the PTO. The PTO took the position that there were multiple inventions disclosed in the original application, and required "restriction" of the original application to just one of the disclosed inventions, pursuant to 35 U.S.C. § 121. Thus, the PTO required Lilly to pursue a number of different patents, through what are known as "divisional applications," relating to different aspects of the basic discoveries underlying the Prozac invention.

In response to this PTO requirement, Lilly initially prosecuted claims directed to the disclosed chemical compounds. These proceedings were severely complicated by numerous patentability inquiries from the PTO that required numerous responses by Lilly and three appeals to the PTO Board of Appeals.

Promptly upon completion of the PTO's examination of these compound claims in 1986, Lilly undertook a review of its original application to determine whether there remained any disclosed inventions that should be claimed. Such a review at the close of patent prosecution was and is customary. That review revealed that the basic invention of using fluoxetine to block serotonin uptake in brain neurons had not yet been patented. Accordingly, claims to that invention were promptly presented and the Molloy patent issued on December 2, 1986.

Given the complexity of the discoveries underlying Prozac, this twelve-year prosecution history is not at all unusual. Indeed, a lengthy prosecution period is typical where any *one* of the following factors is present: (1) the application discloses multiple inventions resulting in PTO requirements to restrict the initial application to only one of the disclosed inventions;[1] (2) PTO rejections must be appealed to the PTO Board of Appeals;[2] or (3) the invention is basic and the patent claims are broad.[3] Given that *all* of these factors were present here, the patent prosecution history of Prozac is not surprising, and Respondents have never asserted that Lilly may be guilty of laches or of inequitable conduct designed intentionally to delay issuance of the Molloy patent.

In addition to the basic patents that issued on the basic discoveries underlying the Prozac invention, numerous patents have issued on a variety of follow-on, "new-use" discoveries that have grown out of the initial breakthroughs. Indeed, the public disclosure of Lilly's

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[1] *See, e.g., Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 357 (Fed. Cir. 1968) (14-year delay resulting in part from restriction requirement); *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279 (Fed. Cir. 1988) (15-year delay resulting in part from restriction requirement); *In re Henriksen*, 399 F.2d 253, 262 (C.C.P.A. 1968) (20-year delay resulting from prosecution of continuing applications).

[2] *See, e.g., General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992) (10-year delay resulting from appeal to PTO Board of Appeals).

[3] *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 727 (6th Cir. 1897) (Taft, J.) ("[T]he course of an application for a generic or broad invention may legitimately take longer in its course through the patent office than a comparatively unimportant improvement on that invention.").

basic inventions led to an explosion of research and discovery in this field. More than 5,500 research papers have been published on fluoxetine, and at least eleven additional United States patents were sought and issued for nonobvious new medical uses of fluoxetine. Only two of these new-use inventions were discovered and patented by Lilly, while nine were discovered and patented by others.

One of these new-use discoveries was the discovery by Lilly's Dr. Stark, made years after Molloy's basic inventions had been published as "prior art," that fluoxetine could be used to treat anxiety in humans. Stark's discovery was embodied in a 1983 patent application that referred the PTO specifically to the published text of Molloy's basic patent application as a related "prior art" invention. Thus, all aspects of each of Molloy's breakthrough discoveries were disclosed as "statutory prior art" against which Stark's claims had to be nonobvious in order to be patentable.

Because of its narrow scope, Stark's patent application did not encounter the examination complexities encountered by the broad, basic application of Molloy. The PTO determined that Stark's new-use invention was both novel, 35 U.S.C. § 102, and nonobvious, 35 U.S.C. § 103, in light of Molloy's earlier invention, and Respondents have never challenged the correctness of that determination. Likewise, the PTO determined that the basic Molloy invention was novel and nonobvious in light of its "prior art." Because the statutory test for separate patentability had been satisfied, the PTO found that Stark and Molloy were entitled to separate patents. In this regard, Stark received the same treatment as the inventors named on at least nine other patents issued by the PTO to scientists not employed by Lilly for separately patentable new uses of fluoxetine.

Stark's new-use improvement patent issued in May of 1986 and was assigned to Lilly. Molloy's basic patent on the special effectiveness of fluoxetine in blocking serotonin uptake in brain neurons issued seven months later, and was also assigned to Lilly. While Lilly's basic Molloy patent has allowed Lilly to market Prozac with exclusivity since 1988, the Stark invention, use of fluoxetine to treat human anxiety, has never even been approved by the Food and Drug Administration ("FDA"). Accordingly, the Stark patent, ironically, has never had any relevance at all to the time during which Lilly could exclusively market Prozac. Indeed, because the Stark patent was commercially and legally irrelevant to Prozac, Lilly disclaimed the Stark patent claims in 1998 in an effort to simplify the issues for trial.

D. Proceedings Below

The case began in 1996 when, prior to the expiration of Lilly's Prozac patents and after Lilly had been marketing Prozac in the United States for only eight years, Respondent Barr Laboratories ("Barr") applied for permission from the FDA to market a generic version of Prozac. Lilly asserted its patent rights against Barr in this suit seeking injunctive relief. Barr challenged the validity of Lilly's Molloy patent on the theory, among others, that it was invalid under the doctrine of "obviousness-type double patenting."

The trial court found that the Respondents' double patenting theories constituted "a confusing amalgamation of broad patent law principles that are not clearly applicable to the [double patenting] issues before the Court" and that the Respondents had "failed to provide any authoritative, reliable scientific opinion" to support their theory. App. 92a & 93a. Accordingly, summary judgment was entered for Lilly on the double patenting issue.

On appeal, a panel of the Federal Circuit twice reversed the entry of summary judgment in Lilly's favor, striking down the Molloy patent as a matter of law. In its initial decision, the panel invalidated the basic Molloy patent on the ground that it constituted an "obvious" double patent in light of Lilly's prior discovery of a generic class of over five million chemical compounds that could be used to treat depression. App. 78a-85a. That prior discovery, according to the panel, rendered "obvious" Lilly's later discovery that one of those compounds, fluoxetine hydrochloride, was especially effective in doing so by virtue of its special effectiveness at blocking the uptake of serotonin in the brain. App. 81a-82a.

After Lilly filed a rehearing petition explaining why the "one in five million" discovery of this use for fluoxetine hydrochloride was a nonobvious discovery, the *en banc* Federal Circuit vacated the panel's decision and remanded the case to the panel for reconsideration. App. 37a. The panel then issued a second decision reaching the same result, but by a completely different analysis. App. 2a. This time, instead of asking whether the invention claimed in the Molloy patent was nonobvious in view of an *earlier* Lilly invention, the panel invalidated the Molloy patent by concluding that the invention it claims was "obvious" as compared to a *later-discovered*, improvement invention – namely, Stark's new-use discovery that fluoxetine is effective in the treatment of human anxiety.

This, according to the Federal Circuit, constituted obviousness-type double patenting notwithstanding that the new-use invention was not discovered by Stark until many years *after* the basic Molloy invention had been both discovered and published as "prior art." Inexplicably, the panel also ruled that Lilly was not allowed to use the well-established remedy in a double-patenting case of

terminally disclaiming that portion of its later-expiring patent that the court had concluded provides an unjustified timewise extension of exclusivity.

Circuit Judge Newman dissented from the court of appeals' refusal *sua sponte* to take the case *en banc*, arguing that double patenting could not be applied where, as here, one of the patented inventions was clearly statutory prior art to the other. App. 43a-49a. In addition, Judge Newman viewed as "unnecessary if not . . . punitive" the court's preemptive ruling that Lilly was not even entitled to protect the validity of its Molloy patent by disclaiming the last seven months of its term. App. 49a.

The Federal Circuit was not receptive to suggestions of continued error in its second opinion. Five *amici*, including the Federal Circuit's own bar association, sought to file briefs supporting Lilly's petition for rehearing of the second opinion. App. 51a-56a. The Federal Circuit denied the motions of the *amici* for leave to file those briefs, without awaiting an opposition brief, and denied Lilly's petition for rehearing on July 18, 2001. App. 51a-56a; App. 95a-96a.

This Petition followed.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW DIRECTLY CONTRADICTS THE STATUTORY REGIME FOR DETERMINING SEPARATE PATENTABILITY.

A. The Federal Circuit Applied a Judge-Made Test That Is the Mirror-Opposite of the Statutory Test.

The patent system is premised on the basic precept that a "new and useful" invention, 35 U.S.C. § 101, can be patented so long as it is novel, *id.* § 102, and nonobvious. *Id.* § 103. In particular, the statutory test for separate

patentability embodied in Section 103 requires the nonobviousness of the invention to be assessed by reference to the "prior art" – that is, the state of knowledge *"at the time the invention was made."* 35 U.S.C. § 103 (emphasis added).[4] Thus, when the prior art discloses a basic invention, the patent statute provides that the follow-on improvement or new-use invention is separately patentable if it is nonobvious in view of the earlier-discovered, basic invention.

The "nonobviousness" requirement operates as a statutory "double patenting" prohibition whenever one of the two patented inventions is prior art to the other. The statutory requirement prohibits issuing two valid patents if the *later-discovered*, follow-on invention is an obvious variation of the *earlier-discovered* prior art invention. Thus, only if the inventions are patentably distinct may two valid patents issue.

In this case, the Federal Circuit imposed a different, wholly unprecedented test for separate patentability that reverses the result mandated by the statute. The issue before the court of appeals was whether Lilly was entitled under the patent statute to own both the Molloy patent and the Stark patent. The Stark invention relates to a new use for the Molloy invention, and was therefore discovered *after* the discovery of the Molloy invention. Specifically, while the Molloy patent claims "a method of blocking the uptake of serotonin by brain neurons in animals" by administering fluoxetine, the Stark patent is directed to "a method for treating anxiety in a human by

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[4] The events that are cognizable as "prior art" under the statute are the events described in 35 U.S.C. § 102. *See Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The text of Molloy's original patent application published in 1977 was "prior art" to Stark under 35 U.S.C. § 102(b).

administering an effective amount of fluoxetine." App. 25a.

It is not disputed that the basic Molloy invention was novel and nonobvious in light of the prior art that existed "at the time the invention was made." 35 U.S.C. § 103. Therefore, it was patentable under the statute. Nor is it disputed that the basic Molloy invention was "prior art" as to the subsequent Stark invention. Thus, the statute clearly resolves any issue of possible double patenting by providing that the two inventions are separately patentable – two patents rather than just one may be granted – so long as the later-discovered Stark invention is nonobvious in view of the earlier-discovered Molloy invention. As previously noted, in accordance with this clear statutory test, the inventions of Molloy and Stark were assessed by the PTO and found to be separately patentable. The correctness of the PTO's determination stands unchallenged. Accordingly, under the statute, two wholly separate patents, with two wholly separate and independent terms, may issue on these inventions, free from any possibility of double patenting.

The Federal Circuit, however, reversed the statutory nonobviousness inquiry, asking the opposite question – whether the *earlier-discovered* prior art invention was nonobvious in light of the *later-discovered* new-use invention. In other words, the court of appeals did not assess whether the Molloy basic invention was nonobvious in view of the "*prior* art" that existed "at the time the invention was made," as required by Section 103. Rather, it assessed the obviousness of the Molloy invention in view of the *subsequent* art that came into existence approximately nine years *after* the invention was discovered.

Plainly, as a matter of law and as a matter of common sense, an invention can be tested for obviousness under

Section 103 *only* against the inventions that precede it – the "prior art" – and not against inventions that have yet to be discovered. A basic invention will *always* be rendered obvious when it is compared, in hindsight, against a later-discovered "new use" invention that simply builds upon the basic invention. Thus, it was only by asking the nonsensical question of whether the basic Molloy invention was nonobvious from its later-discovered "new use" improvement that the court was able to invalidate the basic Molloy patent.[5]

The court of appeals asked this nonsensical question because it focused solely upon the order in which the Molloy and Stark patents issued, rather than the order in which the inventions were discovered. In doing so, the court rendered a decision that conflicts not only with the dictates of the patent statute, but also with venerable legal precedent. In 1897, Judge William Howard Taft of the Sixth Circuit faced an identical set of facts and an identical argument – that a patent on a basic invention should be invalid because it issued after, and was not patentably distinct from, a patent on a later-discovered

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[5] The decision below is especially ironic given that, as explained above, the FDA has never approved the use of the invention underlying Stark, and Stark's claims have thus in no way added to Lilly's ability to market Prozac with exclusivity. What's more, Lilly disclaimed all of the Stark claims in 1998, turning Stark into a pure "shell" patent, existing in name only. Given the hollow nature of the Stark patent and the reasoning that led the Federal Circuit to conclude that Molloy's 1974 discovery was obvious in view of Stark's 1983 discovery, the panel's decision amounts to a $4 billion fine against Lilly based on the perception, wholly unsupported in the record, that Lilly took too much time in prosecuting its Molloy patent. *See infra* Section I, C.

improvement on that invention.[6] *Thomson-Houston Elec. Co. v. Ohio Brass*, 80 F. 712 (6th Cir. 1897). Judge Taft rejected this argument, holding that "the date of the application, and not the date of the patent, controls in determining the legal effect to be given to two patents issued at different dates to the same inventor, and the order in which they are to be considered." *Id.* at 726.

Thus, the decision in *Ohio Brass* squarely considered and rejected the argument that "the later granting of the patent for the main invention extends the monopoly of the earlier improvement patent," *id.* at 726, and squarely held that "a patent for an improvement may expire before the patent for the main invention." *Id.* at 727. Moreover, in reaching this conclusion, Judge Taft explicitly considered this Court's decision in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894), a case relied upon heavily by Respondents. Far

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[6] As Judge Taft stated:

> The argument runs thus: The monopoly of the first patent, the one for the improvement, can legally be of no longer duration than 17 years. But the improvement cannot be used except as applied to the main invention, and, as the later patent (the one for the main invention) does not expire until some time after the expiration of the patent for the improvement, the monopoly of the improvement patent is in fact extended until the expiration of the later patent (the one for the main invention), and so exceeds the statutory 17 years.

Ohio Brass, 80 F. at 726.

After perfectly summarizing the rationale that guided the Federal Circuit's decision in this case, Judge Taft rejected it: "[W]e cannot yield to the argument based on such a distinction, because we cannot accept its minor premise, to wit, that the later granting of the patent for the main invention extends the monopoly of the earlier improvement patent." *Id.*

from supporting Respondents' double-patenting argument, however, the *Miller* Court, as Judge Taft noted,

> distinctly recognize[d] . . . "that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent," and "that a later patent may be granted where the invention is clearly distinct from and independent of the one previously patented." *It is, of course, true that, if an improvement is an invention separable from the generic invention, the latter is an invention distinct and separable from the improvement.* Hence it follows from . . . *Miller v. Manufacturing Co.* that *a patent for a generic invention is not avoided by the fact that a prior invention has been issued for a distinct improvement on that invention.*

Ohio Brass, 80 F. at 728, quoting *Miller v. Eagle Mgf. Co.*, 151 U.S. at 199 (emphasis added).

The panel's decision directly conflicts with Judge Taft's decision in *Ohio Brass*, effectively overturning, *sub silentio*, a precedent that has been recognized and followed as good law for more than a century. *See, e.g., In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991) (citing *Ohio Brass* for proposition that "when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention"); *In re Stanley*, 214 F.2d 151, 155 (C.C.P.A. 1954) (citing *Ohio Brass* for its conclusion "that a later issued generic patent was not invalid because of an earlier issued but later filed improvement patent over the generic invention").

B. The Doctrine of Double Patenting Has Never Been Applied to Two Inventions That the Statute Dictates Are Separately Patentable.

It is not in dispute that the patent law abhors issuing two separate patents for the same or an obvious variation

of the same invention. The controversy here is instead centered on the operable test for determining whether two patented inventions are the *same or obvious variations of the same invention* such that double patenting has taken place.

By requiring that a claimed invention be nonobvious in view of the prior art at the time the invention was made, Section 103 ensures, subject only to one exception, that no more than one patent will issue for each, patentably distinct invention – that is, that there can be no "double patents." The *only* exception is the narrow circumstance in which the earlier invention is not included in the prior art of the later invention, so that the statutory test for patentable distinctness cannot be applied.

Ordinarily, of course, *all* earlier related inventions are included in the prior art against which a subsequent invention must be nonobvious in order to qualify for a separate patent under Section 103. Certain prior inventions, however, are statutorily carved out of the prior art, so that Section 103's nonobviousness test for separate patentability cannot be applied. Most notably, after an inventor discloses an original invention to the public, he is given one year under the statute in which to file as many patent applications as he wishes on his invention without having the public disclosure of that invention count against him as prior art. *See* 35 U.S.C. §§ 102(a) & (b). This exception from the statutory test is designed to facilitate the inventor's effort to patent that invention.

With respect to these "carve outs" from prior art, the judge-made doctrine of double patenting has been applied to ensure that all such patents claim patentably distinct inventions. Otherwise, a potentially unlimited number of patents on obvious modifications of a basic invention could be issued at different times, thereby

extending patent protection on a single patentable invention well beyond the 17-year term provided by statute.

Thus, it is solely to fill the statutory void created by the exceptional circumstance where the earlier invention was *not* included in the prior art, and for no other reason, that the judge-made doctrine of double patenting properly exists. Here, the earlier Molloy invention *was* included in the prior art, so that the follow-on Stark invention was subject to the statutory requirement that it be nonobvious in light of that original invention. Under these facts, the doctrine of double patenting simply does not apply. The Federal Circuit's use of double patenting in this case is therefore wholly unprecedented, as Circuit Judge Newman emphasized below. App. 43a-45a.

Indeed, neither the panel nor any of the Respondents has cited a single precedent finding double patenting in a case, like this one, in which the earlier-discovered invention was disclosed as part of the prior art against which the patentability of the later invention was measured. Lilly has found no such authority. The reason is clear: judge-made law cannot intrude into the area where Congress has supplied the complete test for separate patentability in the statutory scheme of Title 35. *See, e.g., Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625-26 (1978) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted."). As Judge Smith observed, concurring in *In re Braithwaite*, 379 F.2d 594, 602 (C.C.P.A. 1967) (Smith, J., concurring), "*If* Section 103 were applicable then obviously there would be no need for this type of 'double patenting.' " (emphasis added).[7]

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[7] Respondents sought to support the Federal Circuit decision on petition for rehearing by citing (1) this Court's decision in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894), which involved two applications by the same inventor, neither of

The long-standing policies of the PTO confirm that the law of double patenting has been applied *only* where the statutory test for separate patentability is inapplicable. For example, as it became clear in the 1960s that certain prior inventions by third parties were going to be included in the prior art against which new inventions would have to be nonobvious in order to pass the statutory nonobviousness test, the PTO announced that it would *not* apply the doctrine of double patenting to these prior inventions. *See* 846 O.G. 687-88 (Jan. 9, 1967), *reprinted in* 5 LESTER HOROWITZ, PATENT OFFICE RULES AND PRACTICE rel. 72, Pub. 605 (Bender Aug. 1997). The PTO reasoned that double patenting is not necessary where the statutory nonobviousness test applies, explaining that "[i]n situations involving cases filed by different inventive entities, regardless of ownership, Sections 102 and 103 of 35 U.S.C. preclude the granting of two or more patents when directed to identical inventive concepts or when one of the concepts would be obvious in view of the other." *Id.*

Similarly, it was only when Congress narrowed the ground covered by Section 103's nonobviousness test in 1984 that the PTO practice on double patenting broadened to fill the resulting void. When Congress acted in

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which was prior art to the other, that both disclosed the exact same invention (*see, e.g., In re Allen*, 343 F.2d 482, 486-87 (C.C.P.A. 1965)); (2) *In re Blattner*, 245 F.2d 491 (C.C.P.A. 1957), which also involved two applications by the same inventor, neither of which was prior art to the other; and (3) *In re Borg*, 392 F.2d 642, 643 (C.C.P.A. 1968), in which the court specifically noted that the PTO had *not* "applied the [earlier filed] patent as evidence of prior art under 35 U.S.C. § 103." The Federal Circuit itself relied on *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998), and *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993). 251 F.3d at 968 n.7. Both of those cases also involved two applications by the same inventor, neither of which was statutory prior art to the other.

1984 to remove certain inventions from consideration as "prior art" under Section 103, *see* 35 U.S.C. § 103(c), the legislative history reflected the congressional expectation that the judge-made law of double patenting would be expanded to fill, as it had before, the area *not* dealt with by the patent statute. 130 CONG. REC. H10,525 (daily ed. Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5834. The PTO did so in December of 1984. *See* 1050 O.G. 316-24 (Dec. 11, 1984).

It would clearly have been unnecessary for Congress to encourage the PTO to implement such an expansion of the law of double patenting if the doctrine already applied in situations where the statute applied. The inevitable implication of this 1984 development is that the doctrine of double patenting manifestly does *not* extend to those situations where Congress provides a statutory standard for separate patentability.

Thus, the Federal Circuit's decision is a sharp departure from the doctrine of double patenting as it has previously been understood. It is, in effect, the creation of a new doctrine that, irrationally and without any legal authority, overrules the results dictated by the patent statute.

C. Neither Laches nor Inequitable Conduct Has Been Alleged in This Case.

As explained above, the patent statute makes clear that Lilly is entitled to two separate patents for the two distinct inventions at issue in this case. The panel's evident concern that the Molloy patent would give Lilly an "unjustified timewise extension" does not justify the panel in overriding the statutorily mandated result that Lilly is entitled to two patents instead of one. Rather, the appropriate legal analysis for the panel's concern is rooted in a claim of laches or inequitable conduct –

namely, that Lilly unreasonably and unlawfully delayed the issuance of the basic Molloy patent.

Indeed, this was precisely the construct framed by then-Judge Taft when confronted with the identical issue over 100 years ago. As noted earlier, *supra* I, A, in *Ohio Brass*, as in this case, the defendant argued that the patent on the plaintiff's basic invention should be void because it issued after the patent claiming a later-discovered improvement on that basic invention. Judge Taft rejected this argument, reasoning in part that an inverted order of issuance has no legal consequence unless it is brought about deliberately:

> [I]t is said [by defendant] that if, by some chance, the application for the fundamental patent is delayed in its course through the patent office until a patent on the avowed improvement has issued, then the patent on the fundamental invention is void. In cases where the delay in the issuing of the patent for the main invention cannot be charged to the laches or fraud of the patentee, such a rule would be a hard one.

Ohio Brass, 80 F. at 724 (6th Cir. 1897) (Taft, J.). Thus, absent laches or fraud, Judge Taft held that "a patent for an improvement may expire before the patent for the main invention." *Id.* at 728.

The legal doctrines of laches and fraud, however, have never been invoked or argued in this case, and the evidence before the district court simply does not support a conclusion that Lilly unreasonably delayed its prosecution of the Molloy patent. Common law notions of laches require at a minimum an unreasonable and inexcusable delay, not just the possibility that action could have been taken sooner. *See A.C. Aukerman Co. v. R.L. Chaides Constr.*

Co., 960 F.2d 1020, 1024 (Fed. Cir. 1992). Here, the evidence shows that Lilly's prosecution of the Molloy patent was entirely reasonable and customary.[8]

Moreover, Respondents raised no such laches defense in the trial court, and they established no record for evaluating the reasonableness of Lilly's conduct in procuring the Molloy patent under a laches standard. Indeed, the record does not even include the full prosecution history of the Molloy patent. Laches simply cannot be raised for the first time on appeal, and certainly cannot fairly be permitted to lurk behind the panel's stated rationale as the disguised basis for stripping Lilly of a property right worth billions of dollars. To the contrary, if the panel was driven to its result by a concern that Lilly unjustifiably delayed its prosecution of the Molloy patent, then not only did it employ the wrong legal analysis and invoke the wrong legal doctrine, but it also manifestly denied Lilly its basic due process right to rebut that concern in an evidentiary proceeding.

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[8] To be sure, the panel did state in a footnote that the claims in the Molloy patent "could have been presented earlier" and that the PTO was not "*solely* responsible" for the long prosecution process, *see* App. 24a-25a & n.7 (emphasis added), but these vague statements hardly support a laches defense. Lilly's conduct here (identifying the need to present additional claims after completing prosecution of certain originally presented claims) is no different from that of the applicants in *In re Allen*, 343 F.2d 482 (C.C.P.A. 1965), and *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992), neither of which provoked judicial criticism.

D. The Decision Below Yields Absurd and Discriminatory Results.

Judge Newman closed her dissent from the Federal Circuit's refusal to hear this case *en banc* with the following plea: "In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purpose." 251 F.3d at 976. Judge Newman's warnings that the panel's ruling was "truly anomalous" and that it "will surely add confusion and uncertainty to patent practice" were not heeded below. Accordingly, unless this Court vacates the decision below, a number of unhappy results will plague the nation's patent system.

1. The Decision Below Irrationally Discriminates Against Owners of Basic Patents.

The discriminatory effect of the rule of law announced by the Federal Circuit is apparent from the following hypothetical. Assume (1) Stark had been a scientist at Merck and the Stark patent was and is owned by Merck, (2) Lilly owned the Molloy patent, and (3) both patents were prosecuted exactly as they were by Lilly. Both patents would be enforceable for their full terms under the Federal Circuit opinion.

Assume further that a third party, such as Pfizer, subsequently acquires both patents. Does the policy that had permitted independent patent terms suddenly turn "about-face" and invalidate the patent on one of the patentably distinct inventions for "double patenting" just because ownership of the patents has changed? Judge Taft in *Ohio Brass* addressed and rejected precisely this proposition as a "reductio ad absurdum." *See* 80 F. 712, 727 (6th Cir. 1897).

Accordingly, like Pfizer in the foregoing example, Lilly should also be entitled to purchase the Stark patent

and similarly enjoy both patent terms. Moreover, this result cannot logically be different simply because Lilly acquired title to the Stark patent by virtue of *employing* Stark rather than *purchasing* the patent. But the Federal Circuit opinion holds otherwise: it says that *only* the owner of the original basic patent is prevented from obtaining a related improvement patent that issued before that basic patent issued. So viewed, the court's ruling is revealed to be both illogical and unjustifiably discriminatory against the owner of the basic patent. He alone is prohibited from enjoying the full terms of both patents.

2. The Decision Below Encourages Patentees To Manipulate the Patent System.

A second hypothetical reveals that the rule of law announced by the Federal Circuit cannot be justified by any countervailing benefit to the public. Assume the issue dates of the Stark and Molloy patents had been reversed, so that the Stark new-use patent issued seven months after, instead of seven months before, the Molloy basic patent. The public would be prohibited from using the Stark invention for precisely the same length of time – 17 years and seven months. Yet under the Federal Circuit's test there would be no "double patenting" because the later-issued Stark patent would not have been obvious from the earlier-issued Molloy patent. Thus, according to the Federal Circuit, the question of whether Lilly keeps both patents as valid and receives full patent protection for 17 years and seven months, or, instead, receives *zero* patent protection, depends not upon the level of harm suffered by the public but rather upon the happenstance of whether the Stark patent issues before, or after, the Molloy patent.

The Federal Circuit's decision undermines the very spirit of innovation that is the touchstone of patent law. If

the decision is allowed to stand, it will create a strong disincentive for further refinements of a new innovation until a patent has issued on the first invention. Surely, no inventor will run the risk of having the validity of its initial groundbreaking work nullified by the "premature" patenting of a subsequent improvement. As this case illustrates, there can be substantial delay in the issuance of a patent on a groundbreaking basic invention, and thus the Federal Circuit's disincentive for innovation will have a profound impact on innovation and patent prosecution. Patent owners will be compelled either not to seek improvement patents, or to delay their issuance until all of the basic patents have been secured.[9]

II. THE FEDERAL CIRCUIT ERRED IN PREEMPTIVELY DENYING LILLY THE STATUTORY RIGHT TO TERMINALLY DISCLAIM THE MOLLOY PATENT.

Even if the Federal Circuit were somehow correct, and Lilly's Stark and Molloy patents were properly considered "double patents," the decision nonetheless reaches a wholly irrational and erroneous result by holding Lilly's Molloy patent invalid in its entirety. That is not how the law of double patenting works. Indeed, that harsh result directly conflicts with the well-settled right of patentees, codified in Section 253 of the patent statute, to "terminally disclaim" their later-expiring patent in

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[9] In this regard, the rule of law announced by the Federal Circuit does nothing to remedy unwarranted prosecution delays, even though that was apparently its intended object. If Lilly had intentionally delayed issuance of the Stark patent 17 years after issuance of the Molloy patent, the public could not use the Stark invention for 34 years. Yet, there would be no "double patenting" under the Federal Circuit's decision because the Stark patent that issued second would be nonobvious from the Molloy patent that issued first.

order to preserve that portion of the patent that does not provide an unjustified timewise extension of patent exclusivity. *See* 35 U.S.C. § 253 ("[A]ny patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.").

The right to make a terminal disclaimer is the right to jettison that portion of the later-expiring "double patent" that has been held to provide an unjustified timewise extension because it extends beyond the expiration date of the earlier patent over which it has been held to be obvious. Such a disclaimer allows the patentee to preserve the remaining portion of the patent – the portion that does not extend beyond the statutory term of the earlier patent – as valid and enforceable. The terminal disclaimer effectively merges the claims of the "double patents" into a single patent enforceable for a single statutory term. *See In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967) (filing of a terminal disclaimer is "tantamount for all practical purposes to having all the claims in one patent"); *see also, e.g., Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992) ("[O]bviousness-type double patenting can be overcome by filing a terminal disclaimer."); *Quad Env't Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 873 (Fed. Cir. 1991) ("Voluntary limitation of the term of the later-issued patent is a convenient response to an obvious-type double-patenting rejection."); *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) ("It is well-established that a common assignee is entitled to proceed with a terminal disclaimer to overcome a rejection based on double patenting of the obviousness type.") (citations omitted).

Thus, even if the Federal Circuit were correct in holding the Molloy basic patent to be an obvious double patent over the Stark new-use patent, Lilly is statutorily entitled to terminally disclaim that portion of the Molloy patent term extending beyond May 20, 2003, and thereby

to preserve the validity of the Molloy patent until that date. The property right thus preserved is worth approximately $4 billion.[10]

Nevertheless, in order to reach in its second opinion the same result it had improperly reached in its first opinion – the complete invalidity of the Molloy patent – the Federal Circuit held that Lilly was *not* entitled to file such a terminal disclaimer. *See* 251 F.3d at 968 n.5. The court's refusal to allow Lilly to file a terminal disclaimer not only contradicts Section 253 and uniform precedents applying it, the decision is also wholly irrational and unfair. In the panel's own words, the whole point of the "judicially-created doctrine of obviousness-type double patenting" is to "prohibit[ ] a party from obtaining an *extension* of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." App. 23a (emphasis added). Accordingly, the whole focus of a double-patenting case is on that portion of the later-expiring patent that *extends* beyond the expiration date of the earlier-expiring patent: that portion of the patent is the unjustified

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[10] While Respondents argued below that other Lilly patents could also be used to invalidate the Molloy patent for double patenting, these arguments were not accepted by the panel. For example, Respondents pointed to Lilly's new-use patents that was issued to Dr. Holland for the use of fluoxetine to treat high blood pressure. That patent cannot support a double patenting holding for all the reasons noted in Section I above with respect to the Stark patent. Moreover, it deals with peripheral effects of fluoxetine outside the brain and cannot, therefore, be linked to blockage of serotonin uptake in brain neurons as claimed in the Molloy patent, which likely explains why the Federal Circuit did not rely on it in its second opinion. Indeed, had the court been able to rely on the Holland patent, it would not have needed to distort the terminal disclaimer statute to reach its desired result because, unlike the Stark patent, the Holland patent is now expired.

timewise extension, and it is *that portion alone* that must be invalidated in order to fulfill the objectives of the doctrine of double patenting.

The Federal Circuit's sole rationale for this preemptive ruling was that Lilly had previously disclaimed all of the claims of the Stark patent in 1998. According to the court, Lilly "cannot now terminally disclaim the [Molloy] patent to expire at the same time the [Stark] patent would have expired had it not been disclaimed." App. 23a n.5.

This proposition, for which the court cited no authority, is self-evidently wrong. The disclaimer statute and the PTO rule implementing it, 37 C.F.R. § 1.321 (2001), impose no requirement that a first patent be maintained in force as a condition precedent to disclaiming a portion of the term of a second patent, nor has any case ever even hinted at this requirement. Moreover, it is utterly irrational and punitive to engraft such a requirement onto the statute. Since Section 253 allows a patentee to preserve the validity of his double patent by disclaiming *only* the portion of that patent extending beyond the statutory term of its earlier-issued twin, it cannot possibly be true that the patentee loses this right because he has *also* disclaimed *all* of the claims in the earlier-issued twin. In such a case, the patentee has, if anything, done more than Section 253 requires in order to preserve the double patent.

Finally, the panel's rationale for denying Lilly the right to use Section 253 underscores the harsh irony of this case. First, the panel ignored the fact that the Stark patent was legally and commercially irrelevant to Lilly, treating it as a robust patent whose statutory term Lilly could not be allowed to extend by the additional seven months contained in the later-issued Molloy patent. The panel then recognized that the Stark patent, having been disclaimed in its entirety, was illusory, and concluded that the Stark patent's illusory nature somehow prevented Lilly from enjoying *any exclusivity* from the Molloy patent, even *during* the Stark patent's original 17-year

term. In short, the panel cast the Stark patent in two irreconcilable roles – first as a robust patent whose term could not be extended through its purported Molloy twin, and then as a kind of "black hole" patent into whose void the Molloy patent vanished entirely.

CONCLUSION

The Federal Circuit in this case has improperly used the judge-made law of "double patenting" to override Congress in a case where the financial stakes could not be higher. More importantly, the decision below conflicts sharply with express provisions of the patent statute and with venerable precedent, and will have irrational and disruptive repercussions throughout the patent system.

For these and the foregoing reasons, it is respectfully requested that this petition for a writ of certiorari be granted.

Respectfully submitted,

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

DECIDED: May 30, 2001

ON PETITION FOR REHEARING EN BANC

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

GAJARSA, *Circuit Judge*.

ORDER

On the petition for rehearing or rehearing *en banc*, the court accepted the petition for rehearing *en banc*. Acting

en banc, the court vacated the panel's original opinion entered on August 9, 2000, which is reported at 222 F.3d 973, 55 USPQ2d 1609 (Fed. Cir. 2000). The *en banc* court reassigned the opinion to the panel for a specific revision of the double patenting section. Based on the conclusions of the panel, the panel's original judgment affirming the district court's determination on the issue of best mode is reaffirmed. The panel's original judgment, which reversed the district court's determination that claim 7 of U.S. Patent No. 4,626,549 ("the '549 patent") is not invalid for double patenting, is reaffirmed, but on a different legal basis.

In December 1995, Barr Laboratories, Inc. ("Barr") filed an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994), seeking approval from the Food and Drug Administration ("FDA") to market fluoxetine hydrochloride as an antidepressant. Fluoxetine hydrochloride is the active ingredient in Eli Lilly and Company's ("Lilly's") antidepressant drug Prozac. Lilly, on April 10, 1996, pursuant to 35 U.S.C. § 271(e)(2)(A) (1994), brought an infringement action in the United States District Court for the Southern District of Indiana, alleging that Barr's ANDA application infringed claim 5 of U.S. Patent No. 4,314,081 ("the '081 patent") and claim 7 the '549 patent. Lilly subsequently brought infringement actions against Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman, all of whom had also filed ANDA applications with the FDA, and the actions were consolidated.

Barr and the other defendants (collectively "Barr") argued, *inter alia*, that claim 5 of the '081 patent and claim 7 of the '549 patent are invalid for failure to comply with

the best mode requirement and that claim 7 of the '549 patent is invalid for double patenting. On cross-motions for summary judgment, the district court held in favor of Lilly, concluding that neither claim violates the best mode requirement and that no double patenting exists.[1] Barr appeals the district court's summary judgment rulings, and Lilly cross-appeals the district court's ruling that Barr was entitled to a jury trial on its invalidity counterclaims. Because we hold that both claims comply with the best mode requirement but that claim 7 of the '549 patent is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Accordingly, we also vacate the district court's ruling that Barr is entitled to a jury trial because we dispose of the validity issues on appeal.

I. BACKGROUND

The present appeal concerns the validity of claim 5 of the '081 patent, which covers the pharmaceutical compound fluoxetine hydrochloride – the active ingredient in Lilly's antidepressant drug Prozac – and claim 7 of the '549 patent, which covers the administration of fluoxetine hydrochloride to inhibit serotonin uptake in an animal's brain neurons.

On January 10, 1974, Lilly filed application Serial No. 432,379 ("the '379 application") containing claims for a class of compounds, therapeutic methods of using those

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[1] All other issues relating to validity were resolved by consent of the parties. As a result, the district court's judgment disposed of all claims at issue.

compounds, and pharmaceutical compositions comprising those compounds. The '379 application named Bryan B. Molloy ("Molloy") and Klaus K. Schmiegel as inventors. After its filing, the '379 application engendered a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy. When the last patent stemming from the '379 application issued in December 1986, the application had spawned four divisional applications, three continuation applications, and six patents. During that twelve-year period, Lilly obtained six patents relating to fluoxetine hydrochloride – the '081 and '549 patents, as well as U.S. Patent Nos. 4,018,895 ("the '895 patent"), 4,194,009 ("the '009 patent"), 4,590,213 ("the '213 patent"), and 4,329,356 ("the '356 patent"). The '213 and '356 patents did not stem from the '379 application, and during the course of this litigation, Lilly disclaimed those patents.

The '009 patent, which expired in April 1994, claimed a class of pharmaceutical compounds, including fluoxetine hydrochloride, for administration in pyschotropically effective amounts. The '895, '213, and '356 patents related to methods for treating particular ailments by administering a pharmaceutical compound within a class of compounds that includes fluoxetine hydrochloride. Specifically, the '895 patent, which expired in April 1994, concerned the treatment of humans suffering from depression; the '213 patent concerned the treatment of humans suffering from anxiety; and the '356 patent concerned the treatment of animals suffering from hypertension.

In December 1995, pursuant to a Paragraph IV certification under the Hatch Waxman Act, *see* 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV),[2] Barr filed an ANDA application seeking FDA approval to market fluoxetine hydrochloride as an antidepressant. Lilly responded by bringing an action in district court under 35 U.S.C. § 271(e)(2)(A),[3] asserting that Barr's ANDA application infringed claim 7 of the '549 patent and claim 5 of the '081 patent.

At the district court, Barr argued that both claims are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for obviousness-type double patenting. With regard to the best mode issue, Barr advanced two independent arguments. First, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol – a starting material necessary to make fluoxetine hydrochloride. Second, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred solvent

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[2] This section provides, in pertinent part, as follows:

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . for which the applicant is seeking approval under this subsection . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

35 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994).

[3] This section provides, in pertinent part, that "[i]t shall be an act of infringement to submit . . . an application under . . . [the Hatch-Waxman Act] . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

for recrystallizing fluoxetine hydrochloride. With regard to the issue of double patenting, Barr advanced three independent arguments, contending that claim 7 of the '549 patent is invalid in light of (1) the '356 and '213 patents, (2) the '895 and '009 patents, and (3) the '081 patent.

On cross motions for summary judgment, the district court held in favor of Lilly, concluding that claim 5 of the '081 patent and claim 7 of the '549 patent do not violate the best mode requirement and that claim 7 is not invalid for double patenting under any of Barr's theories. The district court recognized that Barr contended that claim 7 of the '549 patent is invalid for double patenting over, *inter alia*, the '213 patent because it merely sets forth the "scientific explanation" for the subject matter of that and other Lilly patents. Yet, the district court determined that Barr failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the scientific explanation of what was already claimed in the patents that came before it, including the '213 patent.

This appeal followed. Because these issues concern disparate parts of the record evidence, we describe separately the background relevant to each argument.

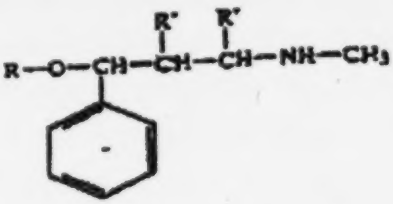
The Claims at Issue

A. Claim 5 of the '081 patent

Stemming directly from the '379 application, the '081 patent issued on February 2, 1982. Claim 5 of the '081

patent, which depends from claim 1, covers the compound N-methyl 3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride – and pharmaceutically-acceptable acid addition salts thereof formed with non-toxic acids. Claim 1, in turn, provides as follows:

A compound of the formula



wherein each R' is independently H or CH sub3 and R is m- or p-chlorophenyl, o-, m-, or p-methoxyphenyl, phenyl, o- or m-fluorophenyl, o- or p-tolyl, 2,4-difluorophenyl or p-trifluoromethylphenyl and acid addition salts formed with pharmaceutically-acceptable acids.

B. Claim 7 of the '549 patent

On March 31, 1986, Lilly filed continuation-in-part application Serial No. 846,448, claiming the benefit of the 1974 filing date of the '379 application under 35 U.S.C. § 120.[4] On December 2, 1986, the application matured into the '549 patent. Claim 7 of the '549 patent, which depends

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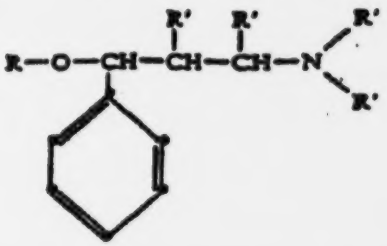
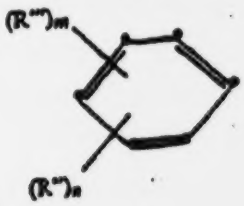
[4] Application Serial No. 846,448 was a continuation-in-part of Serial No. 544,654 (October 24, 1983), which was a continuation of Serial No. 872,147 (January 25, 1978), which in turn was a divisional of Serial No. 432,379 (January 10, 1974).

on claim 4, relates to blocking the uptake of the monoamine serotonin in an animal's brain neurons through administration of the compound N-methyl-3- (p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride. Claim 4 provides as follows:

> A method of blocking the uptake of monoamines by brain neurons in animals comprising administering to said animal a monoamine blocking amount of a compound of the formula



> wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



> wherein R" and R' " are halo, trifluoromethyl, C sub1 -C sub4 alkyl, C sub1 -C sub3 alkyloxy or C sub3 -C sub4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with pharmaceutically-acceptable acids.

C. Best Mode: p-trifluoromethylphenol

Both the '081 and '549 patents identify p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. During the early stages of experimentation, Molloy used commercial p-trifluoromethylphenol purchased from Marshallton Research Laboratories. However, when large quantities of p-trifluoromethylphenol were necessary for clinical testing, Lilly's division director refused to purchase p-trifluoromethylphenol due to the high costs. Instead, he required that Molloy and his colleagues synthesize their own p-trifluoromethylphenol.

To that end, Molloy worked with Lilly scientist Edward Lavagnino ("Lavagnino") to devise a cost-efficient method of synthesizing p-trifluoromethylphenol. After experimenting with various prior art methods, Molloy concluded that those methods were inadequate for generating a sufficient amount of p-trifluoromethylphenol for use in clinical testing. Then, following further research, Molloy and Lavagnino developed their own method for preparing p-trifluoromethylphenol that, as Lavagnino described in his deposition, was "superior" because it used "real cheap" starting material "available [in] tank car quantities." Also, in an article written after the filing of the '379 application, Molloy described his new synthesizing method as an improvement over prior art, because the "literature methods for [p-trifluoromethylphenol's] preparation are cumbersome and not easily adapted to large scale operations."

The '081 and '549 patents do not claim the material p-trifluoromethylphenol or a method for synthesizing it, nor do they disclose Molloy's method for synthesizing it.

D. Best Mode: Recrystallization

While experimenting with compounds claimed in the '081 and '549 patents, Molloy recrystallized the compounds in order to remove impurities and enhance their suitability for pharmaceutical use. The recrystallization process involved using a solvent to dissolve a sample of the compound and then separating the desired product in crystalline form from the impurities that remained dissolved. Between February 1973 and January 1974, Molloy and other Lilly scientists experimented with various solvents for recrystallizing fluoxetine hydrochloride and eventually found a particular solvent that produced a higher yield and higher purity than other solvents.

The record evidence illustrates that while Lilly scientists knew that some solvents for recrystallizing fluoxetine hydrochloride were more effective than others, choosing a suitable recrystallization solvent was well known to one of ordinary skill in the art. In particular, Dr. Elias J. Corey ("Corey"), a Nobel laureate, testified that fluoxetine hydrochloride is "generally quite easy to purify by recrystallizaton." Corey also explained that, although it requires some experimentation, selecting a recrystallization solvent is "very straightforward." Further, Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine."

The '081 and '549 patents do not claim a process for recrystallizing fluoxetine hydrochloride nor do they disclose any solvents for use in the recrystallizing fluoxetine hydrochloride.

E. Double Patenting: The '213 patent

On May 20, 1986, the '213 patent issued from an application filed on April 8, 1983. Claim 1 of the '213 patent provides:

> A method for treating anxiety in a human subject in need of such treatment which comprises the administration to such human an effective amount of fluoxetine or norfluoxetine or pharmaceutically acceptable salts thereof.

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*. *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994). Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.2d 978, 980, 41 USPQ2d 1440, 1442 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Anderson*, 477 U.S. at 248; *General Mills*, 103 F.2d at 980, 41 USPQ2d at 1442.

When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits. *Anderson*, 477 U.S. at 252-53. Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563, 41 USPQ2d 1225, 1232 (Fed. Cir. 1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *Anderson*, 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed. Cir. 1995).

III. BEST MODE

Pursuant to § 112, ¶ 1, a patent specification must set forth the "best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1 (1994). The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge

of the preferred embodiments for practicing the claimed invention. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987) (quoting *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)).

Our case law explicating the best mode requirement focuses on a two-prong inquiry. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996). Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. *Fonar*, 107 F.3d at 1548, 41 USPQ2d at 1804; *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036-37.

With respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention. *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20

USPQ2d 1300, 1302 (Fed. Cir. 1991). Accordingly, an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention. *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998). Furthermore, the best mode requirement does not extend to production details or routine details. *Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1143, 42 USPQ2d 1589, 1594-95 (Fed. Cir. 1997). Production details, which do not concern the "quality or nature of the [claimed] invention," *see id.* at 1143, 42 USPQ2d at 1595, relate to commercial and manufacturing considerations such as equipment on hand, certain available materials, prior relationships with suppliers, expected volume of production, and costs, *see Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581, 21 USPQ2d 1123, 1128 (Fed. Cir. 1991) (explaining that a "step or source or technique considered 'best' in a manufacturing circumstance may have been selected for a non-'best mode' reason"). Routine details, on the other hand, implicate the quality and nature of invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art. *Young Dental*, 112 F.3d at 1143, 42 USPQ2d at 1595.

At the district court, Barr advanced two independent reasons for invalidating the '081 and '549 patents for failure to disclose the best mode: (1) Lilly failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol, and (2) it failed to disclose Molloy's

preferred solvent for recrystallizing the fluoxetine hydrochloride compound. On cross-motions for summary judgment, the district court held in favor of Lilly. Barr appeals, and we address each argument in turn.

A. Synthesizing p-trifluoromethylphenol

Barr contends that claim 5 of the '081 patent and claim 7 of the '549 patent do not meet the best mode requirement because the patents fail to disclose Molloy's method for synthesizing p-trifluoromethylphenol. In the present case, even assuming that Molloy preferred his method for synthesizing p-trifluoromethylphenol to alternative means of obtaining the material, we hold that failure to disclose the synthesizing method does not contravene the best mode requirement.

We begin our analysis by examining the scope of the claimed inventions. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("The best mode inquiry is directed to what the applicant regards as his invention, which in turn is measured by the claims."). Claim 5 of the '081 patent covers a formula for the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for blocking the uptake of serotonin by brain neurons through administering a dosage of fluoxetine hydrochloride. Example 1 in both the '081 and '549 patents identifies the chemical p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. Neither patent, however, claims p-trifluoromethylphenol itself or a method for synthesizing it. Thus, while the best mode for developing fluoxetine hydrochloride involves use of p-trifluoromethylphenol, the claimed inventions

do not cover p- trifluoromethylphenol and the patents do not accord Lilly the right to exclude others from practicing Molloy's method for synthesizing p-trifluoromethylphenol. As a result, the best mode requirement does not compel disclosure of Molloy's unclaimed method for synthesizing p-trifluoromethylphenol.

Furthermore, the circumstances here are different from those in *Dana Corp. v. IPC Ltd.*, 860 F.2d 415, 418, 8 USPQ2d 1692 (Fed. Cir. 1988), and *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-41, 15 USPQ2d 1321, 1328 (Fed. Cir. 1990), in which an inventor failed to disclose unclaimed subject matter that was necessary for carrying out the best mode of the invention. In the present case, Molloy disclosed his preference for using p-trifluoromethylphenol when making fluoxetine hydrochloride. What he did not disclose, nor was he required to do so, was the unclaimed method for synthesizing p-trifluoromethylphenol. *Cf. Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 590, 7 USPQ2d 1050, 1054 (Fed. Cir. 1988) (finding no violation of best mode requirement by concealment of a preferred cleaning fluid formula when the claimed invention "neither added nor claimed to add anything to the prior art respecting cleaning fluid").

To be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter even if it is unclaimed. *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998); *Wahl Instruments*, 950 F.2d at 1583-84, 21 USPQ2d at 1130. That, however, is not the case here. In the present case, the record insistently

demonstrates that p-trifluoromethylphenol was commercially available at the time Lilly filed its original application. The record includes a product catalog from Marshallton Research Laboratories, dated January 1973, offering to sell p-trifluoromethylphenol. The record also contains an expert witness report explaining that p-trifluoromethylphenol was commercially available before 1974 from Aldrich Chemical Company. Additionally, the record includes prior art references that describe methods for preparing p-trifluoromethylphenol.

Barr contends that *Clayton v. Akiba*, 214 USPQ 374, 1982 WL 50444 (Bd. Pat. App. 1982), supports its position that Lilly was obligated to disclose the method for synthesizing p-trifluoromethylphenol. We do not find that argument persuasive. *Clayton*, aside from being non-binding on this court, involves facts that are inapposite to the present case. In *Clayton*, the claimed invention was a chemical compound, and the Board found that the inventor violated the best mode requirement by failing to disclose his method for preparing a necessary intermediate compound. *See id.* at 380-81. The Board's reasoning, however, hinged on the fact that the intermediate compound was "*itself admittedly a novel compound* . . . and, thus, its preparation [was] part and parcel of 'carrying out' the invention." *Id.* at 381 (emphasis added). Here, by contrast, the chemical p-trifluoromethylphenol, as explained above, was commercially available and described in the prior art.

Barr also seizes upon portions of the record evidence in an effort to establish a best mode violation. For example, Barr relies on Lavagnino's deposition testimony

that Molloy's method for synthesizing p-trifluoromethylphenol used material "available in tank car quantities, real cheap chemical, and simple transformations." Barr also cites Lavagnino's statement explaining that Molloy's synthesizing method could be "scaled up" to produce large amounts of p-trifluoromethylphenol. Barr points to Molloy's own statement that "the relatively high cost" of p-trifluoromethylphenol "is a limiting factor in its use as a chemical intermediate," and that he preferred his synthesizing method because other methods were "cumbersome and not easily adapted to large scale operations." Finally, Barr relies on evidence that Lilly stopped purchasing p-trifluoromethylphenol after Molloy developed his synthesizing method.

Rather than establishing a best mode violation, this amalgam of evidence provides paradigmatic examples of production details that the law excepts from best mode disclosure. Indeed, this evidence relates to considerations of costs, volume, and available resources for manufacturing fluoxetine hydrochloride, all details that are superfluous to the best mode requirement. *See Wahl Instruments*, 950 F.2d at 1581-82, 21 USPQ2d at 1128-29 (holding no best mode violation for failure to disclose a method chosen for reasons of cost and volume). In short, the reasons for using Molloy's synthesizing method were not linked to the intrinsic quality of fluoxetine hydrochloride, which is the thrust of the best mode requirement.

B. Recrystallization Solvent

Barr also argues that claim 5 of the '081 patent and claim 7 of the '549 patent violate the best mode requirement because Molloy failed to disclose the particular recrystallization solvent that he used to purify fluoxetine hydrochloride. Even assuming that Molloy preferred a particular and specific recrystallization solvent to others, we hold that failure to disclose that solvent does not violate the best mode requirement.

Once again, we begin our analysis with the scope of the claimed invention. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302. Claim 5 of the '081 patent covers the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for administering it. Both patents teach that the preferred embodiment of fluoxetine hydrochloride is achieved by purifying the compound through recrystallization. Based on the record, there is no genuine issue that one of ordinary skill in the art possessed the requisite knowledge to select a solvent for recrystallizing fluoxetine hydrochloride. Even Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine." Choosing a solvent for performing recrystallization, therefore, constitutes a routine detail that falls outside the ambit of the best mode disclosure. *See Young Dental*, 112 F.3d at 1144, 42 USPQ2d at 1595; *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 ("It is well established that what is within the skill of the art need not be disclosed to satisfy the best mode requirement as long as that mode is described.").

Barr contends that, even if choosing a solvent for recrystallization is a routine detail, the best mode requirement compels Molloy to disclose the particular and specific solvent he used in the recrystallization process. In effect, Barr argues that Molloy was obligated to disclose not only the preferred embodiment of the claimed invention, but also the preferred solvent for the unclaimed recrystallization process. Stated at a higher level of generality, Barr asserts that a patentee must disclose a preferred mode for carrying out an unclaimed routine detail. That position, however, is in conflict with the scope of the claims at issue, our prior decisions, and the purpose undergirding the best mode requirement.

As we have often said, "[i]t is concealment of the best mode of practicing the *claimed invention* that § 112, ¶ 1 is designed to prohibit." *Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036 (emphasis added). Here, the patents disclose that the best mode of the claimed invention is fluoxetine hydrochloride that is purified through recrystallization. The patents, however, do not claim a process for purifying fluoxetine hydrochloride through recrystallization or a solvent for performing the recrystallization. Thus, failure to disclose a preferred solvent does not equate to a best mode violation because the patents simply do not claim a recrystallization process or a recrystallization solvent. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless and the pitfalls endless."); *cf. Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1288, 55 USPQ2d 1065, 1070 (Fed. Cir. 2000) (holding no best mode violation

when inventor did not disclose an unclaimed, preferred method for use of the claimed invention – thin-line etching – because the claim covered a general process of plasma etching and the patent described the best mode for carrying out that process).

Further, § 112 requires only "an adequate disclosure of the best mode." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1025-26 (Fed. Cir. 1991). It logically follows that a patentee's failure to disclose an unclaimed, preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention. Indeed, Barr and other companies are able to recrystallize fluoxetine hydrochloride by using solvents different from the one Molloy used. In addition, our cases hold that a patentee complies with § 112 even though some experimentation is necessary to practice the best mode. *See id.* (holding that best mode does not require a "guarantee that every aspect of the specification be precisely and universally reproducible"); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1579-80 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986). In *Hybritech*, for example, this court held that the patentee did not violate § 112, even though carrying out the best mode of the invention involved screening experiments that were laborious and time consuming, because screening methods were known in the art. 802 F.2d at 1384-85, 231 USPQ at 94. Similarly, in the present case, solvents for recrystallizing fluoxetine hydrochloride were known in

the art, and simply because selecting a desired solvent may have required some experimentation, nondisclosure of Molloy's particular solvent does not rise to a best mode violation.

Moreover, the purpose behind the best mode requirement supports our conclusion. As we explained in *Amgen*, the best mode requirement establishes a *quid pro quo* whereby the patentee "must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode." 927 F.2d at 1210, 18 USPQ2d at 1024. The best mode requirement, however, is a two-way street, and in the present case, the '081 and '549 patents do not grant Lilly the right to exclude others from practicing Molloy's method of recrystallization or from using his preferred solvent. Thus, it would be incongruous to require that Molloy disclose that information nonetheless. *See Randomex*, 849 F.2d at 588, 7 USPQ2d at 1053 ("It is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." (emphasis in original)).

In sum, because no genuine issue of material fact exists upon which a reasonable jury could find that claim 5 and claim 7 did not comply with the best mode requirement, we affirm the district court's grant of summary judgment in favor of Lilly. Thus, we have no occasion to determine if Barr has a right to a jury trial on that issue.

III. DOUBLE PATENTING

Through a statutorily prescribed term, Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention. 35 U.S.C. § 154(a)(2)

(1994). The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent. *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (explaining that, even though no explicit statutory basis exists for obviousness-type double patenting, the doctrine is necessary to prevent a patent term extension through claims in a second patent that are not patentably distinct from those in the first patent).[5] As one of our predecessor courts explained, "[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Van Ornum*, 686 F.2d 937, 943-44, 214 USPQ 761, 766 (CCPA 1982) (quoting *In re Schneller*, 397 F.2d 350, 158 USPQ 210, 214 (CCPA 1968)).

Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in

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[5] A patent owner cannot avoid double patenting by disclaiming the earlier patent. Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term or, as in this case, is the date it is terminated via disclaimer.

the later patent and determines the differences.[6] *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999). Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. *Id.* at 1327, 52 USPQ2d at 1595. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. *In re Berg*, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998). A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim. *In re Longi*, 759 F.2d at 896, 225 USPQ at 651 (affirming a holding of obviousness-type double patenting because the claims at issue were obvious over claims in four prior art patents); *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998) (affirming a holding of obviousness-type double patenting where a patent application claim to a genus is anticipated by a patent claim to a species within that genus).

On appeal, we limit our inquiry to an analysis of whether claim 7 of the '549 patent is invalid for obvious-type double patenting over claim 1 of the '213 patent.[7] In

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[6] An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim.

[7] A two-way double patenting test does not apply in this case. The two-way test is only appropriate in the unusual circumstance where, *inter alia*, the United States Patent and Trademark Office ("PTO") is "*solely* responsible for the delay in causing the second-filed application to issue prior to the first." (emphasis added). *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at

accordance with the two-prong obviousness-type double patenting test demarcated in *Georgia-Pacific*, we first construe the claims at issue and determine the differences in subject matter between these two claims. The relevant portion of claim 1 of the '213 patent is directed to a method for treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically-acceptable salt thereof. '213 patent, col. 2, ll. 34-39. Claim 7 of the '549 patent covers a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride. '549 patent, col. 20, ll. 7-9.

A person of ordinary skill in the art would have recognized that fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine. In fact, hydrochloride salts are the most common pharmaceutically acceptable salts of basic drugs, and hence are obvious compounds. *See, e.g., The Merck Index of Chemicals and*

1233 (Fed. Cir. 1998); *see also In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993) (holding that PTO actions did not dictate the rate of prosecution when Goodman accepted early issuance of species claims and filed a continuation application to prosecute genus claims). Such circumstances are not present in this case, because the PTO was not solely responsible for the delay. Indeed, the '549 patent issued in December 1986, approximately eight months after a continuation-in-part was filed, which stemmed from a continuation application, which in turn stemmed from a divisional of the original '379 application that was filed in January 1974. Further, an expert hired on behalf of Lilly in the matters of PTO and corporate intellectual property practice, in discussing claim 7 of the '549 patent, stated: "[I]t is true that the claim could have been presented earlier. . . . " This statement indicates that the delay was not solely caused by the PTO.

Drugs (Paul G. Stecher et al. eds., 7th ed. 1960) (listing multiple hydrochloride salts of drugs).

Therefore, the only difference between claim 1 of the '213 patent and claim 7 of the '549 patent is that the former addresses a method of treating anxiety in humans with fluoxetine hydrochloride while the latter claims a method of using fluoxetine hydrochloride to block serotonin uptake in animals. Having recognized the difference between the claims at issue, we must decide whether this difference renders the claims patentably distinct.

Serotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal, such as a human, for any purpose, including the treatment of anxiety. That is, serotonin uptake inhibition is an inherent property of fluoxetine hydrochloride upon its administration. Barr has offered a panoply of evidence to support the recognition of this inherent biological function of fluoxetine hydrochloride.

In Lilly's March 24, 1998 10-K filing with the Securities and Exchange Commission, Lilly pointed out that serotonin uptake inhibition is the "process by which Prozac works." The title of a 1995 article published by Lilly also indicates that Prozac is a serotonin uptake inhibitor: *Minireview Prozac (Fluoxetine, Lilly 110140), The First Selective Serotonin Uptake Inhibitor and Antidepressant Drug: Twenty Years Since Its First Publication.*[8] David T. Wong,

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[8] The reference to "selective" means that fluoxetine hydrochloride inhibits the uptake of serotonin to a greater

Frank P. Bymaster, & Eric A. Engleman, at 1 (1995). The summary of this article "describe[s] the evolutionary process involved in the discovery of the selective 5-HT [serotonin] uptake inhibitor, fluoxetine. . . . "[9] *Id.* at 1. The first full sentence of the article states: "Fluoxetine (Prozac) first appeared in scientific literature as Lilly 110140 (the hydrochloride form), a selective serotonin uptake inhibitor, in the August 15, 1974 issue of *Life Sciences.*" *Id.* The article continues: "After twenty-plus years of extensive investigations, inhibition of serotonin uptake remains the major mechanism of action for fluoxetine. . . . " *Id.* Several tables in the article specifically demarcate amounts of serotonin uptake inhibition resulting from fluoxetine administration. *Id.* at 7, 10-12, 14, 18. The article even illustrates chemical structures of several serotonin uptake inhibitors, one of which is fluoxetine. *Id.* at 9. The article concludes by stating that despite "intensive investigation," including over 5500 research papers on the subject, fluoxetine "is still regarded as a selective [serotonin] uptake inhibitor."

During a deposition, Lilly's expert, Alan Frazer, divulged that "[t]here is no doubt in my mind" that fluoxetine hydrochloride inhibits serotonin reuptake in "the vast majority" of people that ingest fluoxetine hydrochloride. Frazer also stated that he had "no doubt" that inhibition reuptake in brain neurons is the expected consequence of administering fluoxetine hydrochloide. Frazer further acknowledged in a sworn statement that:

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degree than it inhibits the uptake of other monoamines (such as dopamine or norepinephrine).

[9] The Wong article defines 5-HT as serotonin. Wong at 2.

"Clearly, there are [sic] a wealth of data demonstrating that the uptake of serotonin is inhibited in most humans when fluoxetine is administered." Another one of Lilly's experts, Louis Lemberger, stated in the course of a deposition: "If you give fluoxetine hydrochloride to a human being you are going to inhibit serotonin uptake. . . . " Yet another Lilly expert, Irwin Slater, also agreed that ingesting fluoxetine hydrochloride will result in the inhibition of serotonin uptake in brain neurons.

Likewise, Barr's expert, Fridolin Sulser, stated in an affidavit that "[t]he pharmalogical effect of administering fluoxetine hydrochloride is to inhibit serotonin reuptake in brain neurons." He also recognized that "it is literally impossible to treat someone for anxiety . . . with fluoxetine hydrochloride without at the same time inhibiting serotonin reuptake." In an expert report, Dr. Sulser again reiterated that "the primary pharmalogical effect of fluoxetine is the inhibition of serotonin reuptake in brain neurons." He further reiterated that administering fluoxetine hydrochloride "will inherently and inevitably block the reuptake of serotonin. . . . " He provided a wealth of support for these opinions. Another Barr expert, Robert Roth, also stated that "[t]he biological activity of claim 7 of the '549 patent[ ] inherently and inevitably occurs whenever someone practices . . . the '213 . . . patent[ ]." He continued, stating that "there is no doubt" that "administration of fluoxetine hydrochloride inherently and inevitably blocks the reuptake of serotonin. . . . " Dr. Roth provided a plethora of support for his opinion.

Lilly has not proffered any significant evidence rebutting Barr's ample foundation for the proposition

that administration of fluoxetine hydrochloride naturally and inherently inhibits the uptake of serotonin.

A reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346, 51 USPQ2d 1943, 1945 (Fed. Cir. 1999). A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (citations omitted). In this case, it is clear from all of the evidence proffered by Barr that the natural result flowing from administration of fluoxetine hydrochloride is inhibition of serotonin uptake. Therefore, the limitation of claim 7 of the '549 patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose, including the treatment of anxiety.

A patentable distinction does not lie where a later claim is anticipated by an earlier one. That is, a later patent claim that fails to provide novel invention over an earlier claim is not patentably distinct from the earlier claim. Salient aspects of the case at issue are factually similar to *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 32 USPQ2d 1915 (Fed. Cir. 1994). That case involved several patents directed to the use of 3'-azidothymidine ("AZT") to treat individuals infected with the human immunodeficiency virus ("HIV") or individuals who had acquired immunodeficiency syndrome ("AIDS"), and involved United States Patent No. 4,818,750 ("the '750 patent"), which covered a method of

using AZT to increase the T-lymphocyte count of persons infected with HIV. *Burroughs Wellcome*, 40 F.3d at 1225, 32 USPQ2d at 1916-17. While never directly addressed by the majority, in his partial dissent, Judge Lourie articulated that the '750 patent should have been invalidated for double patenting because the method claimed in the '750 patent "is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS." *Id.* at 1233, 32 USPQ2d at 1924 (Lourie, J., dissenting-in-part). He stated that because the method claimed in the '750 patent was inherent in the use of AZT to treat HIV and AIDS patients, it lacked novelty. *Id.* He continued, suggesting that allowing a common owner to receive both a patent claiming the physical act of treating individuals that have HIV or AIDS and a patent covering the result that such treatment accomplishes makes "no sense." *Id.* at 1234, 32 USPQ2d at 1924. "It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain relieving mechanism by means of that treatment is another." *Id.*

Similarly, in the case at bar, claim 7 of the '549 patent simply describes the process by which fluoxetine hydrochloride physically acts on individuals who receive the drug. That is, fluoxetine hydrochloride inherently blocks serotonin uptake upon administration. Therefore, no patentable distinction rests between administering fluoxetine hydrochloride for treatment of anxiety and inhibition of serotonin uptake by administration of fluoxetine hydrochloride.

The only other difference between claim 1 of the '213 patent and claim 7 of the '549 patent is that the former is directed to humans while the latter is directed to animals.

Humans are a species of the animal genus. Our case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim. *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).

A motion for summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if there is sufficient evidence for a jury to return a verdict in favor of the nonmoving party on the particular issue. *Anderson*, 477 U.S. at 248. While the burden rests on the party moving for summary judgment to show "that there is an absence of evidence to support the non-moving party's case," the nonmoving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 325. In this case, Barr moved for summary judgment that claim 7 of the '549 patent was invalid for double patenting over, *inter alia*, claim 1 of the '213 patent. Barr has presented an abundance of evidence indicating that the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake. Lilly has not proffered sufficient evidence in response to this evidence. Therefore, there remains no

genuine issue of fact as to this issue. That is, there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin. Accordingly, the district court erred by indicating that Barr failed to establish that inhibition of serotonin uptake merely describes a biological result of fluoxetine hydrochloride administration for the treatment of anxiety. Further, there is no issue of fact as to whether a human is a species of the animal genus or whether fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine. Consequently, the double patenting issue in this case is solely a matter of law.

We have compared the differences between the claims at issue as a whole and conclude that they are not patentably distinct. Therefore, we reverse the district court's denial of the portion of Barr's motion for summary judgment contending that claim 7 of the '549 patent is invalid for obviousness-type double patenting over claim 1 of the '213 patent. Consequently, the portion of Barr's motion for summary judgment pertaining to double patenting is granted. The district court's grant of Lilly's motion for summary judgment pertaining to double patenting is reversed.

IV. CONCLUSION

Because we hold that claim 5 of the '081 patent and claim 7 of the '549 patent comply with the best mode requirement and that claim 7 is invalid for obviousness-type double patenting in view of claim 1 of the '213 patent, we affirm-in-part and reverse-in-part. Further,

because we do not reach the issue, we vacate the district court's grant of a jury trial to Barr.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND VACATED.

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-cross appellant, Eli Lilly and Company. With him on the brief were *Allen M. Sokal, Kenneth M. Frankel,* and *David S. Forman.* Of counsel was *L. Scott Burwell.* Of counsel on the brief were *Douglas K. Norman,* and *James P. Leeds,* Eli Lilly and Company, of Indianapolis, Indiana.

Richard S. Clark, Rochelle K. Seide, Marta E. Delsignore, Louis Sorell, Robert Neuner, and *Thomas J. Parker,* Baker & Botts, of New York, New York, for defendant-appellant, Geneva Pharmaceuticals, Inc.

George C. Lombardi, Winston & Strawn, of Chicago, Illinois, argued for defendant-appellant Barr Laboratories, Inc. With him on the brief were *James F. Hurst, Dan K. Webb, Bradley C. Graveline, Christine J. Siwik*, and *Taras A. Gracey*. Of counsel on the brief was Mark E. Waddell, Bryan Cave, LLP, of New York, New York. Of counsel was *Derek John Sarafa*.

Hugh L. Moore, and *Diane I. Jennings*, Lord, Bissell & Brook, of Chicago, Illinois for defendants-appellants Apotex, Inc. and Bernard C. Sherman.

Jeffrey P. Kushan, Powell, Goldstein, Frazer & Murphy LLP, of Washington, DC, for amicus curiae Biotechnology Industry Organization. Of counsel on the brief were *Richard Medway* and *Eric M. Solovy*, Powell, Goldstein, Frazer & Murphy LLP; and *Charles E. Ludlam*, Biotechnology Industry Organization, of Washington, DC.

William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, for amicus curiae Zenith Goldline Pharmaceuticals, Inc.

Joseph P. Lavelle, Howrey Simon Arnold & White, of Washington, DC, for amicus curiae Intellectual Property Owners Association.

John C. Vassil, Morgan & Finnegan, L.L.P., of New York, New York, for amicus curiae Federal Circuit Bar Association. With him on the brief were *Michael P. Dougherty, Tony V. Pezzano*, and *Tini Thomas*. Of counsel on the brief were *George E. Hutchinson* and *Philip C. Swain*, Federal Circuit Bar Association, of Washington, DC.

Janice M. Mueller, Associate Professor, The John Marshall Law School, of Chicago, Illinois, amicus curiae.

Nancy J. Linck, Guilford Pharmaceuticals Inc., of Baltimore, Maryland, for amicus curiae Guilford Pharmaceuticals Inc.

Appealed from: United States District Court for the Southern District of Indiana

Chief Judge Sara Evans Barker

United States Court of Appeals for the Federal Circuit

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ORDER

Eli Lilly and Company filed a combined petition for panel rehearing and rehearing en banc. Responses thereto were invited by the court, and filed by Geneva Pharmaceuticals, Inc., and Barr Laboratories, Inc. The petition for rehearing and responses[1] were referred to the panel

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[1] Amicus curiae briefs were filed by:

a- Intellectual Property Owners Association
b- Federal Circuit Bar Association
c- Professor Janice M. Mueller
d- Guilford Pharmaceuticals Inc.

that heard the appeal, and thereafter, referred to the circuit judges who are in regular active service.

Acting *en banc*, the court accepted the petition for rehearing en banc, and vacated the panel's opinion entered on August 9, 2000, which is reported at 222 F.3d 973 (Fed. Cir. 2000). The en banc court reassigned the appeals to the panel, which issues a separate opinion today.

Circuit Judge Newman dissents in a separate opinion.

Circuit Judge Linn did not participate in the vote.

FOR THE COURT,

MAY 30 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

MAY 30 2001

JAN HORBALY
CLERK

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e- Biotechnology Industry Organization
f- Zenith Goldline Pharmaceuticals, Inc.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

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Chief Judge Sarah Evans Barker

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99-1262, -1263, -1264, -1303

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Defendants-Appellants,

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INTERPHARM, INC.,

Defendant.

NEWMAN, *Circuit Judge,* dissenting from the refusal to reconsider the case *en banc.*

The Federal Circuit, sitting *en banc,* vacated the panel's prior opinion issued on August 9, 2000 and returned the case to the panel for further consideration. The panel now again holds claim 7 of the '549 (Molloy) patent invalid for double patenting, but this time it bases that determination on a different patent, the '213 patent (Stark). The panel now grants summary judgment invalidating claim 7 of the '549 patent for double patenting with the Stark patent. However, this shift has led the panel into factual and legal areas that were not developed at trial, and into misapplication and misstatement of the law of double patenting. I must, respectfully, dissent.

Obviousness-Type Double Patenting

The judge made law of obviousness-type double patenting was developed to cover the situation where patents are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting thus is applied when neither patent is prior art against the other, usually because they have a common priority date. *See General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278-81, 23 USPQ2d 1839, 1843-46 (Fed.Cir.1992) (summarizing the criteria for obviousness-type double patenting). As the court explained in *In re Boylan*, 392 F.2d 1017, 1018 n.1, 157 USPQ 370, 371 n.1 (CCPA 1968), "it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act."

These fundamental requirements for application of the law of double patenting are not met by the '549 and Stark patents. The Stark patent was filed nine years after the effective filing date of the '549 patent; there is no formal relationship between them; the '549 disclosure was a cited reference against Stark; and they have different inventorships. The panel ignores these routine criteria and the effect they have on a double patenting analysis. Whatever effect the '549 and Stark patents may have on each other, it is not "double patenting."

The district court had rejected Barr's double patenting arguments after summary judgment proceedings, ruling that:

> Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the "scientific explanation" for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before.

On presumably the same record, the panel now grants summary judgment and *sua sponte* finds double patenting between claim 7 of the '549 patent and claim 1 of the Stark patent. The '549 disclosure, in the form of three issued divisional patents, was prior art cited against the Stark patent. Patentability of the Stark claims over this prior art was successfully argued in the PTO. The panel reaches the anomalous conclusion that the earlier filed '549 patent (effective filing date January 10, 1974) is invalid for obviousness-type double patenting with the Stark patent that was filed nine years later (April 8, 1983). Such a result is not available under the laws of 35 U.S.C.

§102 and §103; neither can it be achieved under the rubric of double patenting.

The claims are:

Claim 7 of the '549 Molloy patent:

> The method of claim 4 [blocking the uptake of monoamines by brain neurons in animals] comprising administering to said animal a monoamine blocking amount of N-methyl-3-p-trifluoromethylphenoxy-3-phenylproplyamine [fluoxetine] or a pharmaceutically-acceptable acid addition salt thereof.

Claim 1 of the '213 Stark patent:

> A method for treating anxiety in a human subject in need of such treatment which comprises the administration to said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically-acceptable salts thereof.[1]

The panel holds that the later-discovered and later-filed anxiety-treatment use of fluoxetine invalidates the patent on the earlier discovery of monoamine (serotonin) blocking use because the earlier discovery is "inherent" in the later one. That is not a correct statement of either the law of double patenting or the law of inherency. The 1974 invention can not be invalidated based on what was filed and claimed in the 1983 application, even on the panel's incorrect view of the law of inherency as applied to biological inventions.

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[1] A biological property or new use of a composition is claimed as a "method of use," in accordance with 35 U.S.C. 101. Both claim 7 of the '549 patent and claim 1 of the Stark patent are method-of-use claims.

The district court remarked on the absence of reliable evidence as well as legal precedent to support Barr's proffered theories. The panel, however, finds that "Barr has offered a panoply of evidence to support the recognition of this inherent biological function." Panel op. at 23. I take note that the panel cites only references dated after the '549 application was filed. These references are not prior art to the '549 claims. Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work.

The complex factual issues that have been raised in the record, in connection with the relationship between serotonin uptake and the various pharmaceutical uses of fluoxetine, can not be resolved in favor of Barr and adversely to Lilly on the summary judgment record, for the material facts have been placed squarely at issue. Indeed, the scientific evidence in the record weighs heavily against the panel's findings.

It is highly relevant that the Stark application was examined in light of prior art that included the '549 Molloy disclosure. While Barr cites cases that established rules with respect to the subsequent patentability of a genus when a species is known, this has no relevance to the question at bar. Further, these rules relate to whether a subsequent invention is patentable, not a prior one. Here, however, it is the first-filed (Molloy) invention that the panel invalidates in view of the later-filed Stark invention. Although the Stark patent issued seven months before the '549 patent, the panel incorrectly holds that the later-filed but earlier-issued Stark claim renders

obvious the '549 claim of nine years earlier priority. Neither *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir.1998), relied on by the panel, nor any other case, supports such an inverted holding.

When two patents issue with claims that are not patentably distinct, the principle served by the judge made law of double patenting is that because patent protection started with the first patent to issue, it should not extend to the expiration of the second patent to issue. Thus the law of double patenting does not consider the patents as prior art; the law simply requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue.

When the second patent to issue is (as here) the first patent that was filed, an anomaly may arise when there is a valid charge of obviousness-type double patenting. I repeat, that charge is not here available because the first patent that was filed was in fact a reference against the second patent. The panel, ignoring this immutable fact, undertakes an obviousness-type double patenting analysis. When two patents are appropriately considered for obviousness-type double patenting, an anomaly arises, for example, when the claims of patent B are "obvious" in light of the claims of patent A, but the claims of patent A are not obvious in light of the claims of patent B. An illustration is shown in In re Berg, where one patent was directed to a species, and the other to a genus that included the species. A genus is usually not patentable over a species, but a species may, depending on the facts, be patentable over the genus. Judge made law has developed a special and simple test for double patenting in

such a situation: the requirement of "cross-reading." By applying the rules of cross-reading, double patenting will not lie, for cases in which the first patent to issue is the second patent that was filed, unless the claims cross read; that is, unless the claims of each patent would have been obvious in view of the claims of the other patent. This simple expedient avoids the analytical trap into which the panel fell.

The panel has reached the truly anomalous result of holding invalid for obviousness, on a theory of obviousness-type double patenting, an invention that was made and applied for nine years before the asserted "prior art" was filed.

The panel states that *In re Berg* requires that unless the PTO is solely and exclusively responsible for all delays in issuing the first-filed patent, the patentee can not rely on the fact of its earlier filing. That is not the *Berg* holding. In *Berg* the same inventors filed, on the same day, patent applications whose claims stood in the relationship of genus and species of the same method for preparing an abrasive particle suitable for use in an abrasive composition. When the species application was about to issue, the examiner rejected the genus application on the grounds of obviousness-type double patenting. Berg argued that each application should be evaluated as to whether it represented a patentable advance over the other, a two-way test of cross-reading applied in particular circumstances. This court stated that the purpose of the two-way test, as it had been developed in our precedent, was "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but,

through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." The Federal Circuit then held that Berg was not entitled to the benefits of the two-way test because he could have included all of the claims in a single application. Neither the facts of Berg nor the law as developed therein applies to the patents here under consideration.

The panel also holds that because Lilly disclaimed the Stark patent before trial, this bars Lilly from disclaiming that portion of the '549 patent that would have extended beyond the Stark patent's original life. No precedent so holds, and I discern no basis for such a new rule. A terminal disclaimer is a standard response to a charge of double patenting; this remedy need not be withheld, at least in the absence of fraud or bad faith. To deny a patentee the opportunity of simplifying the issues or improving its litigation position is an unnecessary if not a punitive action, unwarranted on this record.

The New Rules of Patentability of Biological Inventions

The panel states that "the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake," and holds that a discovery of a new and unobvious biological property is unpatentable because it is inherent in the chemical compound. As authority the panel cites a dissenting opinion in *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1233, 32 USPQ2d 1915, 1924 (Fed.Cir.1994) (Lourie, J. dissenting in part), the dissent

suggesting that a patent to a method which "is an inherent, inevitable result of the practice" of another method patent constitutes same-invention double patenting. Thus the panel holds the '549 claim to serotonin inhibition to be invalid as the natural and inherent result of the Stark treatment for relief of anxiety. However, every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered. To negate the patentability of a discovery of biological activity because it is "the natural result" of the chemical compound can have powerful consequences for the patentability of biological inventions. The narrow facts of *Burroughs Wellcome* and the dissenting view therein do not warrant the new rule now adopted.

The panel also states that "there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin." Indeed, it is far from clear what could be proved, as well as what must be proved, on the panel's theory of double patenting, for the many scientific articles cited in the record show the complexity of the mechanism of action of fluoxetine. However, the panel's ruling that Lilly would have to prove that serotonin inhibition does not occur on treatment with fluoxetine, in order to avoid double patenting invalidity of its claim for serotonin inhibition on treatment with fluoxetine, will surely add confusion and uncertainty to patent practice.

In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purposes.

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

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BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

ORDER

The Biotechnology Industry Organization (BIO) moves for leave to file, and to set a time to file, an amicus curiae brief in support of Eli Lilly and Company's (Lilly) combined petition for rehearing and rehearing en banc.

BIO states that Lilly consents to this motion, while the Appellants do not consent.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is denied.

FOR THE COURT,

JUN 15 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Joseph P. Lavelle, Esq.
William L. Mentlik, Esq.
John C. Vassil, Esq.
Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 15 2001
JAN HORBALY
CLERK

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, NEWMAN, MICHEL, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, and DYK, *Circuit Judges*.

ORDER

The Biotechnology Industry Organization ("BIO") moves for en banc reconsideration, joined by the Pharmaceutical Research and Manufacturers of America, the National Association of Manufacturers, and the Federal

Circuit Bar Association, of the panel's June 15, 2001, order denying BIO leave to file, and to set a time to file, an amicus curiae brief in support of Eli Lilly and Company's combined petition for rehearing and rehearing en banc.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

NEWMAN, LOURIE, RADER, and DYK, *Circuit Judges*, would allow the brief to be filed. LINN, *Circuit Judge*, did not participate in the vote.

FOR THE COURT,

JUN 27 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Herbert C. Warnsley, Esq.
William L. Mentlik, Esq.
John C. Vassil, Esq.
Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 27 2001
JAN HORBALY
CLERK

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, NEWMAN, MICHEL, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, and DYK, *Circuit Judges*.

ORDER

The Intellectual Property Owners Association ("IPO") moves for leave to file an amicus curiae brief in support of Eli Lilly and Company's combined petition for rehearing and rehearing en banc. IPO indicates that Barr

Laboratories, Inc. has not consented to the filing of this amicus brief.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

NEWMAN, LOURIE, RADER, and DYK, *Circuit Judges*, would allow the brief to be filed. LINN, *Circuit Judge*, did not participate in the vote.

FOR THE COURT,

JUN 27 2001
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
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FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUN 27 2001
JAN HORBALY
CLERK

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

DECIDED: August 9, 2000

Before MAYER, *Circuit Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

GAJARSA, *Circuit Judge*.

Barr Laboratories, Inc. ("Barr"), in December 1995, filed an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994), seeking approval from the Food and Drug Administration ("FDA") to market fluoxetine hydrochloride as an antidepressant. Fluoxetine hydrochloride is the active ingredient in Eli Lilly and

Company's ("Lilly's") antidepressant drug Prozac. Lilly, on April 10, 1996, pursuant to 35 U.S.C. § 271(e)(2)(A) (1994), brought an infringement action in the United States District Court for the Southern District of Indiana, alleging that Barr's ANDA application infringed claim 5 of U.S. Patent No. 4,314,081 ("the '081 patent") and claim 7 of U.S. Patent No. 4,626,549 ("the '549 patent"). Lilly subsequently brought infringement actions against Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman, all of whom had also filed ANDA applications with the FDA, and the actions were consolidated.

Barr and the other defendants (collectively "Barr") argued, *inter alia,* that claim 5 of the '081 patent and claim 7 of the '549 patent are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for double patenting. On cross-motions for summary judgment, the district court held in favor of Lilly, concluding that neither claim violates the best mode requirement and that no double patenting exists.[1] Barr appeals the district court's summary judgment rulings, and Lilly cross-appeals the district court's ruling that Barr was entitled to a jury trial on its invalidity counterclaims. Because we hold that both claims comply with the best mode requirement but that claim 7 of the '549 patent is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Accordingly, we also vacate the district court's ruling that Barr is entitled to a

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[1] All other issues relating to validity were resolved by consent of the parties. As a result, the district court's judgment disposed of all claims at issue.

jury trial because we dispose of the validity issues on appeal.

I. BACKGROUND

The present appeal concerns the validity of claim 5 of the '081 patent that covers the pharmaceutical compound fluoxetine hydrochloride – the active ingredient in Lilly's antidepressant drug Prozac – and claim 7 of the '549 patent that covers the administration of fluoxetine hydrochloride to inhibit serotonin uptake in an animal's brain neurons.

On January 10, 1974, Lilly filed application Serial No. 432,379 ("the '379 application") containing claims for a class of compounds, therapeutic methods of using those compounds, and pharmaceutical compositions comprising those compounds. The '379 application named Bryan B. Molloy ("Molloy") and Klaus K. Schmiegel as inventors. After its filing, the '379 application engendered a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy. When the last patent stemming from the '379 application issued in December 1986, the application had spawned four divisional applications, three continuation applications, and six patents. During that twelve-year period, Lilly obtained six patents relating to fluoxetine hydrochloride – the '081 and '549 patents, as well as U.S. Patent Nos. 4,018,895 ("the '895 patent"), 4,194,009 ("the '009 patent"), 4,590,213 ("the '213 patent"), and 4,329,356 ("the '356 patent"). The '213 and '356 patents did not stem from the '379 application, and during the course of this litigation, Lilly disclaimed those patents.

The '009 patent, which expired in April 1994, claimed a class of pharmaceutical compounds, including fluoxetine hydrochloride, for administration in pyschotropically effective amounts. The '895, '213, and '356 patents related to methods for treating particular ailments by administering a pharmaceutical compound within a class of compounds that includes fluoxetine hydrochloride. Specifically, the '895 patent, which expired in April 1994, concerned the treatment of humans suffering from depression; the '213 patent concerned the treatment of humans suffering from anxiety; and the '356 patent concerned the treatment of animals suffering from hypertension.

In December 1995, pursuant to a Paragraph IV certification under the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994),[2] Barr filed an ANDA application seeking FDA approval to market fluoxetine hydrochloride as an antidepressant. Lilly responded by bringing an action in district court under 35 U.S.C.

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[2] This section provides, in pertinent part, as follows:

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . for which the applicant is seeking approval under this subsection . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

35 U.S.C. § 355(j)(2)(A)(vii)(IV).

§ 271(e)(2)(A) (1994),[3] asserting that Barr's ANDA application infringed claim 7 of the '549 patent and claim 5 of the '081 patent.

At the district court, Barr argued that both claims are invalid for failure to comply with the best mode requirement and that claim 7 of the '549 patent is invalid for obviousness-type double patenting. With regard to the issue of best mode, Barr advanced two independent arguments. First, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol – a starting material necessary to make fluoxetine hydrochloride. Second, Barr argued that the claims are invalid because the patents failed to disclose Molloy's preferred solvent for recrystallizing fluoxetine hydrochloride. With regard to the issue of double patenting, Barr advanced three independent arguments, contending that claim 7 of the '549 patent is invalid in light of (1) the '356 and '213 patents, (2) the '895 and '009 patents, and (3) the '081 patent.

On cross motions for summary judgment, the district court held in favor of Lilly, concluding that claim 5 of the '081 patent and claim 7 of the '549 patent do not violate the best mode requirement and that claim 7 is not invalid for double patenting under any of Barr's theories. This appeal followed. Because these issues concern disparate

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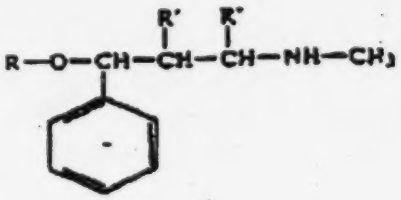
[3] This section provides, in pertinent part, that "[i]t shall be an act of infringement to submit . . . an application under . . . [the Hatch-Waxman Act] . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

parts of the record evidence, we describe separately the background relevant to each argument.

The Claims at Issue

A. Claim 5 of the '081 patent

Stemming directly from the '379 application, the '081 patent issued on February 2, 1982. Claim 5 of the '081 patent, which depends on claim 1, covers the compound N-methyl 3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride – and pharmaceutically-acceptable acid addition salts thereof formed with non-toxic acids. Claim 1, in turn, provides as follows:

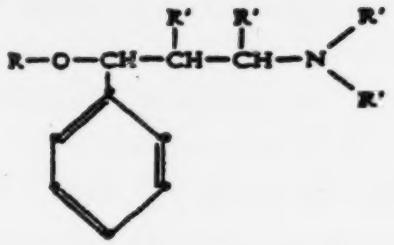
> A compound of the formula
>
> 
>
> wherein each R' is independently H or CH_3 and R is m- or p-chlorophenyl, o-, m-, or p-methoxyphenyl, phenyl, o- or m-fluorophenyl, o- or p-tolyl, 2,4-difluorophenyl or p-trifluoromethylphenyl and acid addition salts formed with pharmaceutically-acceptable acids.

B. Claim 7 of the '549 patent

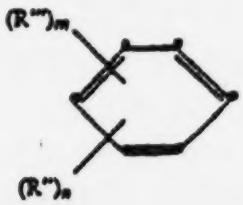
On March 31, 1986, Lilly filed continuation application Serial No. 846,448, claiming the benefit of the 1974 filing date of the '379 application under 35 U.S.C. § 120.

On December 2, 1986, the application matured into the 549 patent. Claim 7 of the '549 patent, which depends on claim 4, relates to blocking the uptake of the monoamine serotonin in an animal's brain neurons through administration of the compound N-methyl-3-(p-trifluoromethylphenoxy)-3-phenylpropylamine hydrochloride – commonly referred to as fluoxetine hydrochloride. Claim 4 provides as follows:

> A method of blocking the uptake of monoamines by brain neurons in animals comprising administering to said animal a monoamine blocking amount of a compound of the formula



wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



wherein R" and R'" are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with pharmaceutically-acceptable acids.

C. Best Mode: p-trifluoromethylphenol

Both the '081 and '549 patents identify p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. During the early stages of experimentation, Molloy used commercial p-trifluoromethylphenol purchased from Marshallton Research Laboratories. However, when large quantities of p-trifluoromethylphenol were necessary for clinical testing, Lilly's division director refused to purchase p-trifluoromethylphenol due to the high costs. Instead, he required that Molloy and his colleagues synthesize their own p-trifluoromethylphenol.

To that end, Molloy worked with Lilly scientist Edward Lavagnino ("Lavagnino") to devise a cost efficient method of synthesizing p-trifluoromethylphenol. After experimenting with various prior art methods, Molloy concluded that those methods were inadequate for generating a sufficient amount of p-trifluoromethylphenol for use in clinical testing. Then, following further research, Molloy and Lavagnino developed their own method for preparing p-trifluoromethylphenol that, as Lavagnino described in his deposition, was "superior" because it used "real cheap" starting material "available [in] tank car quantities." Also, in an article written after the filing of the '379 application, Molloy described his new synthesizing method as an improvement over prior art, because the "literature methods for [p-trifluoromethylphenol's] preparation are cumbersome and not easily adapted to large scale operations."

The '081 and '549 patents do not claim the material p-trifluoromethylphenol or a method for synthesizing it, nor do they disclose Molloy's method for synthesizing it.

D. Best Mode: Recrystallization

While experimenting with compounds claimed in the '081 and '549 patents, Molloy recrystallized the compounds in order to remove impurities and enhance their suitability for pharmaceutical use. The recrystallization process involved using a solvent to dissolve a sample of the compound and then separating the desired product in crystalline form from the impurities that remained dissolved. Between February 1973 and January 1974, Molloy and other Lilly scientists experimented with various solvents for recrystallizing fluoxetine hydrochloride and eventually found a particular solvent that produced a higher yield and higher purity than other solvents.

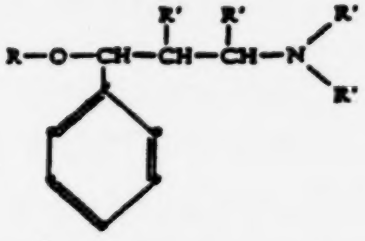
The record evidence illustrates that while Lilly scientists knew that some solvents for recrystallizing fluoxetine hydrochloride were more effective than others, choosing a suitable recrystallization solvent was well known to one of ordinary skill in the art. In particular, Dr. Elias J. Corey ("Corey"), a Nobel laureate, testified that fluoxetine hydrochloride is "generally quite easy to purify by recrystallizaton." Corey also explained that, although it requires some experimentation, selecting a recrystallization solvent is "very straightforward." Further, Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine."

The '081 and '549 patents do not claim a process for recrystallizing fluoxetine hydrochloride nor do they disclose any solvents for use in the recrystallizing fluoxetine hydrochloride.

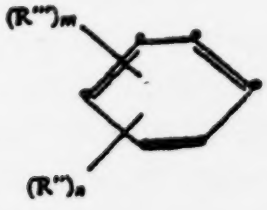
E. Double Patenting: The '895 patent

On March 4, 1977, divisional application Serial No. 514,094 matured into the '895 patent. Claim 1 of the '895 patent, the only independent claim, provides as follows:

> A method of treating human suffering from depression which comprises administering to said human an effective antidepressant dose of a compound of the formula:



> wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



> wherein R" and R"' are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition

salts thereof formed with a pharmaceutically-acceptable acid.

Put differently, claim 1 of the '895 patent covers the administration of a pharmaceutical compound within a class of claimed compounds to treat depression in humans. The '895 patent expired in April 1994.

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*. *See Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 U.S.P.Q.2d 1373, 1377 (Fed. Cir. 1994). Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.2d 978, 980, 41 U.S.P.Q.2d 1440, 1442 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *See Anderson*, 477 U.S. at 248; *General Mills*, 103 F.2d at 980, 41 U.S.P.Q.2d at 1442.

When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits. *See Anderson*, 477 U.S. at 252-53. Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282 (1994), which can be overcome only through clear and convincing evidence, *see United*

States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563, 41 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *See Anderson*, 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274, 35 U.S.P.Q.2d 1035, 1038 (Fed. Cir. 1995).

III. BEST MODE

Pursuant to section 112, ¶ 1, a patent specification must set forth the "best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1 (1994). The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987) (quoting *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)).

Our case law explicating the best mode requirement focuses on a two-prong inquiry. *See Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036-37 (Fed. Cir. 1990). First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *See Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996). Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. *See Fonar*, 107 F.3d at 1548, 41 USPQ2d at 1804; *U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. *See U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *See U.S. Gypsum*, 74 F.3d at 1212, 37 USPQ2d at 1390; *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036-37.

With respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention. *See Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 USPQ2d 1300, 1302 (Fed. Cir. 1991). Accordingly, an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention. *See Applied Med. Resources Corp. v. United States*

Surgical Corp., 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998). Furthermore, the best mode requirement does not extend to production details or routine details. *See Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1143, 42 USPQ2d 1589, 1594-95 (Fed. Cir. 1997). Production details, which do not concern the "quality or nature of the [claimed] invention," *see id.* at 1143, 42 USPQ2d at 1595, relate to commercial and manufacturing considerations such as equipment on hand, certain available materials, prior relationships with suppliers, expected volume of production, and costs, *see Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581, 21 USPQ2d 1123, 1128 (Fed. Cir. 1991) (explaining that a "step or source or technique considered 'best' in a manufacturing circumstance may have been selected for a non-'best mode' reason"). Routine details, on the other hand, implicate the quality and nature of invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art. *See Young Dental*, 112 F.3d at 1143, 42 USPQ2d at 1595.

At the district court, Barr advanced two independent reasons for invalidating the '081 and '549 patents for failure to disclose the best mode: (1) Lilly failed to disclose Molloy's preferred method for synthesizing p-trifluoromethylphenol, and (2) it failed to disclose Molloy's preferred solvent for recrystallizing the fluoxetine hydrochloride compound. On cross motions for summary judgment, the district court held in favor of Lilly. Barr appeals, and we address each argument in turn.

A. Synthesizing p-trifluoromethylphenol

Barr contends that claim 5 of the '081 patent and claim 7 of the '549 patent do not meet the best mode requirement because the patents fail to disclose Molloy's method for synthesizing p-trifluoromethylphenol. In the present case, even assuming that Molloy preferred his method for synthesizing p-trifluoromethylphenol to alternative means of obtaining the material, we hold that failure to disclose the synthesizing method does not contravene the best mode requirement.

We begin our analysis by examining the scope of the claimed inventions. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302 ("The best mode inquiry is directed to what the applicant regards as his invention, which in turn is measured by the claims."). Claim 5 of the '081 patent covers a formula for the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for blocking the uptake of serotonin by brain neurons through administering a dosage of fluoxetine hydrochloride. Example 1 in both the '081 and '549 patents identifies the chemical p-trifluoromethylphenol as a starting material for making fluoxetine hydrochloride. Neither patent, however, claims p-trifluoromethylphenol itself or a method for synthesizing it. Thus, while the best mode for developing fluoxetine hydrochloride involves use of p-trifluoromethylphenol, the claimed inventions do not cover p-trifluoromethylphenol and the patents do not accord Lilly the right to exclude others from practicing Molloy's method for synthesizing p-trifluoromethylphenol. As a result, the best mode requirement does not compel disclosure of Molloy's

unclaimed method for synthesizing p-trifluoromethylphenol.

Furthermore, the circumstances here are different from those in *Dana Corp. v. IPC Ltd., Partnership*, 860 F.2d 415, 418, 8 USPQ2d 1692 (Fed. Cir. 1988), and *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-41, 15 USPQ2d 1321, 1328 (Fed. Cir. 1990), in which an inventor failed to disclose unclaimed subject matter that was necessary for carrying out the best mode of the invention. In the present case, Molloy disclosed his preference for using p-trifluoromethylphenol when making fluoxetine hydrochloride. What he did not disclose, nor was he required to do so, was the unclaimed method for synthesizing p-trifluoromethylphenol. *Cf. Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 590, 7 USPQ2d 1050, 1054 (Fed. Cir. 1988) (finding no violation of best mode requirement by concealment of a preferred cleaning fluid formula when the claimed invention "neither added nor claimed to add anything to the prior art respecting cleaning fluid").

To be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter even if it is unclaimed. *See Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 USPQ2d 1289, 1291 (Fed. Cir. 1998); *Wahl Instruments*, 950 F.2d at 1583-84, 21 USPQ2d at 1130. That, however, is not the case here. In the present case, the record insistently demonstrates that p-trifluoromethylphenol was commercially available at the time Lilly filed its original application. The record includes a product catalog from Marshallton Research

Laboratories, dated January 1973, offering to sell p-trifluoromethylphenol. The record also contains an expert witness report explaining that p-trifluoromethylphenol was commercially available before 1974 from Aldrich Chemical Company. Additionally, the record includes prior art references that describe methods for preparing p-trifluoromethylphenol.

Barr contends that *Clayton v. Akiba*, 214 USPQ 374 (Bd. Pat. App. 1982), supports its position that Lilly was obligated to disclose the method for synthesizing p-trifluoromethylphenol. We do not find that argument persuasive. *Clayton*, aside from being non-binding on this court, involves facts that are inapposite to the present case. In *Clayton*, the claimed invention was a chemical compound, and the Board found that the inventor violated the best mode requirement by failing to disclose his method for preparing a necessary intermediate compound. *See id.* at 380-81. The Board's reasoning, however, hinged on the fact that the intermediate compound was "*itself admittedly a novel compound* . . . and, thus, its preparation [was] part and parcel of 'carrying out' the invention." *Id.* at 381 (emphasis added). Here, by contrast, the chemical p-trifluoromethylphenol, as explained above, was commercially available and described in the prior art.

Barr also seizes upon portions of the record evidence in an effort to establish a best mode violation. For example, Barr relies on Lavagnino's deposition testimony that Molloy's method for synthesizing p-trifluoromethylphenol used material "available in tank car quantities, real cheap chemical, and simple transformations." Barr also cites Lavagnino's statement explaining

that Molloy's synthesizing method could be "scaled up" to produce large amounts of p-trifluoromethylphenol. Barr points to Molloy's own statement that "the relatively high cost" of p-trifluoromethylphenol "is a limiting factor in its use as a chemical intermediate," and that he preferred his synthesizing method because other methods were "cumbersome and not easily adapted to large scale operations." Finally, Barr relies on evidence that Lilly stopped purchasing p-trifluoromethylphenol after Molloy developed his synthesizing method.

Rather than establishing a best mode violation, this amalgam of evidence provides paradigmatic examples of production details that the law excepts from best mode disclosure. Indeed, this evidence relates to considerations of costs, volume, and available resources for manufacturing fluoxetine hydrochloride, all details that are superfluous to the best mode requirement. *See Wahl Instruments*, 950 F.2d at 1581-82, 21 USPQ2d 1128-29 (holding no best mode violation for failure to disclose a method chosen for reasons of cost and volume). In short, the reasons for using Molloy's synthesizing method were not linked to the intrinsic quality of fluoxetine hydrochloride, which is the thrust of the best mode requirement.

B. Recrystallization Solvent

Barr also argues that claim 5 of the '081 patent and claim 7 of the '549 patent violate the best mode requirement because Molloy failed to disclose the particular recrystallization solvent that he used to purify fluoxetine hydrochloride. Even assuming that Molloy preferred a

particular and specific recrystallization solvent to others, we hold that failure to disclose that solvent does not violate the best mode requirement.

Once again, we begin our analysis with the scope of the claimed invention. *See Engel Indus.*, 946 F.2d at 1531, 20 USPQ2d at 1302. Claim 5 of the '081 patent covers the compound fluoxetine hydrochloride, and claim 7 of the '549 patent covers a method for administering it. Both patents teach that the preferred embodiment of fluoxetine hydrochloride is achieved by purifying the compound through recrystallization. Based on the record, there is no genuine issue that one of ordinary skill in the art possessed the requisite knowledge to select a solvent for recrystallizing fluoxetine hydrochloride. Even Barr's expert testified that "in 1974, sometimes the recrystallization of amine hydrochlorides was indeed routine." Choosing a solvent for performing recrystallization, therefore, constitutes a routine detail that falls outside the ambit of the best mode disclosure. *See Young Dental*, 112 F.3d at 1144, 42 USPQ2d at 1595; *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 ("It is well established that what is within the skill of the art need not be disclosed to satisfy the best mode requirement as long as that mode is described.").

Barr contends that, even if choosing a solvent for recrystallization is a routine detail, the best mode requirement compels Molloy to disclose the particular and specific solvent he used in the recrystallization process. In effect, Barr argues that Molloy was obligated to disclose not only the preferred embodiment of the claimed invention but also the preferred solvent for the unclaimed

recrystallization process. Stated at a higher level of generality, Barr asserts that a patentee must disclose a preferred mode for carrying out an unclaimed routine detail. That position, however, is in conflict with the scope of the claims at issue, our prior decisions, and the purpose undergirding the best mode requirement.

As we have often said, "[i]t is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." *Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036 (emphasis added). Here, the patents disclose that the best mode of the claimed invention is fluoxetine hydrochloride that is purified through recrystallization. The patents, however, do not claim a process for purifying fluoxetine hydrochloride through recrystallization or a solvent for performing the recrystallization. Thus, failure to disclose a preferred solvent does not equate to a best mode violation because the patents simply do not claim a recrystallization process or a recrystallization solvent.

See Engel Indus., 946 F.2d at 1531, 20 USPQ2d at 1302 ("Unclaimed subject matter is not subject to the disclosure requirements of § 112; the reasons are pragmatic: the disclosure would be boundless and the pitfalls endless."); *cf. Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1288, 55 USPQ2d 1065, 1070 (Fed. Cir. 2000) (holding no best mode violation when inventor did not disclose an unclaimed, preferred method for use of the claimed invention – thin-line etching – because the claim covered a general process of plasma etching and the patent described the best mode for carrying out that process).

Further, section 112 requires only "an adequate disclosure of the best mode." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1025-26 (Fed. Cir. 1991). It logically follows that a patentee's failure to disclose an unclaimed, preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention. Indeed, here, Barr and other companies are able to recrystallize fluoxetine hydrochloride by using solvents different from the one Molloy used. In addition, our cases hold that a patentee complies with section 112 even though some experimentation is necessary to practice the best mode. *See id.* (holding that best mode does not require a "guarantee that every aspect of the specification be precisely and universally reproducible"); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1579-80 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986). In *Hybritech*, for example, this court held that the patentee did not violate section 112 even though carrying out the best mode of the invention involved screening experiments that were laborious and time consuming, because screening methods were known in the art. *See* 802 F.2d at 1384-85, 231 USPQ at 94. Similarly, in the present case, solvents for recrystallizing fluoxetine hydrochloride were known in the art, and simply because selecting a desired solvent may have required some experimentation, non-disclosure of Molloy's particular solvent does not rise to a best mode violation.

Moreover, the purpose behind the best mode requirement supports our conclusion. As we explained in *Amgen*, the best mode requirement establishes a *quid pro quo* whereby the patentee "must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode." 927 F.2d at 1210, 18 USPQ2d at 1024. The best mode requirement, however, is a two-way street, and in the present case, the '081 and '549 patents do not grant Lilly the right to exclude others from practicing Molloy's method of recrystallization or from using his preferred solvent. Thus, it would be incongruous to require that Molloy disclose that information nonetheless. *See Randomex*, 849 F.2d at 588, 7 USPQ2d at 1053 ("It is concealment of the best mode of practicing the *claimed invention* that section 112, ¶ 1 is designed to prohibit." (emphasis in original)).

In sum, because no genuine issue of material fact exists upon which a reasonable jury could find that claim 5 and claim 7 did not comply with the best mode requirement, we affirm the district court's grant of summary judgment in favor of Lilly. Thus, we have no occasion to determine if Barr has a right to a jury trial on that issue.

III. DOUBLE PATENTING

Through a statutorily prescribed term, Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention. *See* 35 U.S.C. § 154(a)(2) (Supp. 1998) (discussing the length of a patent term). The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation by

prohibiting a party from obtaining an extension of exclusive rights through claims in a later patent that are not patentably distinct from claims in an earlier patent. *See In re Braat*, 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*. 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (explaining that, even though no explicit statutory basis exists for obviousness-type double patenting, the doctrine is necessary to prevent a patent term extension through claims in a second patent that are not patentably distinct from those in the first patent). As our predecessor court explained, "[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re Van Ornum*, 686 F.2d 937, 943-44, 214 USPQ 761, 766 (CCPA 1982) (quoting *In re Schneller*, 397 F.2d 350, 158 USPQ 210, 214 (1968)).[4]

Obviousness-type double patenting entails a two-step analysis. First, as a matter of law, the court construes the claim in the earlier patent and the claim in the later patent, and it overlays the later claim on the earlier claim to determine whether the later claim encompasses subject matter previously claimed.[5] *See Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326, 52 USPQ2d

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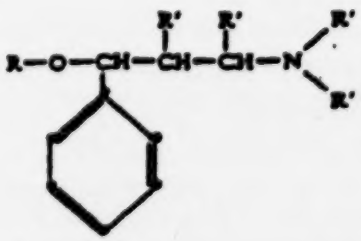
[4] A patentee can cure invalidity for double patenting by filing a terminal disclaimer, thereby foregoing the portion of the term of the later patent that extends beyond the term of the earlier patent. In the present case, however, Lilly did not file a terminal disclaimer with respect to claim 7 of the '549 patent.

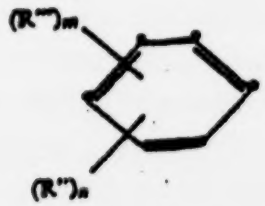
[5] An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim.

1590, 1593 (Fed. Cir. 1999) (stating that "analysis of the claims is the first step" in an obviousness-type double patenting inquiry); *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1844 (Fed. Cir. 1992). Second, the court determines whether the differences in subject matter between the two claims is such that the claims are patentably distinct. *See Georgia-Pacific*, 195 F.3d at 1327, 52 USPQ2d at 1595 (proceeding to determine whether differences between the two claims are patentably distinct after construing the claims); *General Foods*, 972 F.2d at 1279, 23 USPQ2d at 1844 (explaining that the terms "patentably distinguishable," "patentable distinctions," and obvious variations are equivalent for analytical purposes).

At the district court, Barr proffered three independent theories under which it sought to invalidate claim 7 of the '549 patent for obviousness-type double patenting. On appeal, we limit our analysis to claim 1 of the '895 patent. We begin by construing claim 1 of the '895 patent and claim 7 of the '549 patent to determine whether the former covers subject matter subsequently claimed in the latter. Claim 1 of the '895 patent pertains to a method of treating depression in humans by administering a compound within the class of compounds defined by the following formula:



wherein each R' is independently hydrogen or methyl; wherein R is naphthyl or



wherein R" and R'" are halo, trifluoromethyl, C_1-C_4 alkyl, C_1-C_3 alkyloxy or C_3-C_4 alkenyl; and wherein n and m are 0, 1 or 2; and acid addition salts thereof formed with a pharmaceutically-acceptable acid.

Claim 7 of the '549 patent claims a method for administering the compound fluoxetine hydrochloride to inhibit serotonin uptake. Claim 7 depends on claim 4, which claims a method of blocking the uptake of monoamines by administering a compound found within the same class of compounds that is defined by claim 1 of the '895 patent. Thus, fluoxetine hydrochloride covered in claim 7 of the '549 patent is also one of the compounds encompassed by claim 1 of the '895 patent. It necessarily follows that claim 1 of the '895 patent covered the administration of fluoxetine hydrochloride to treat depression.

Lilly argues that selecting fluoxetine hydrochloride from the class of compounds in claim 1 of the '895 patent to treat depression would not have been obvious to one of ordinary skill in the art because that claim covers thousands of possible compounds. That argument, however, is of no consequence because double patenting is not "concerned with what one skilled in the art would be aware [of] from reading the claims but with what inventions the claims define." *In re Sarett*, 327 F.2d 1005, 1013,

140 USPQ 474, 481 (CCPA 1964). Here, claim 1 of the '895 patent, when properly construed, already covered the administration of fluoxetine hydrochloride for treating depression. Further, Lilly's reliance on *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994), and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), is unavailing. In those cases, we held that a species claim is not necessarily obvious in light of a prior art disclosure of a genus. *See Baird*, 16 F.3d at 382, 29 USPQ2d at 1552; *Jones*, 958 F.2d at 350, 21 USPQ2d at 1943. The present case, however, in which the same party *claims* a genus in an earlier patent and then *claims* a species in a later patent is entirely different from cases such as *Baird* and *Jones*, in which the prior art merely *discloses* a genus and a later patent claims a species.

Moreover, we find Lilly's argument to be disingenuous because it seeks to use the broad coverage of claim 1 of the '895 patent as both a sword and a shield. Throughout the term of the '895 patent, by virtue of claim 1's broad coverage, Lilly possessed the right to exclude other parties from administering any of the thousands of claimed compounds, including but not limited to fluoxetine hydrochloride, to treat depression. Thus, for example, if another party attempted to use fluoxetine hydrochloride to treat depression, Lilly could have sued for infringement of the '895 patent or asserted its patent as a dominating patent, *see In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 682 (Fed. Cir. 1986) (explaining that domination exists when a broad claim of an earlier patent reads on a narrower claim of a later patent, such that a party cannot practice the later patent without infringing the earlier patent). As a corollary to that

expansive right of exclusivity, the '895 patent specification satisfied the written description requirement by allowing persons of ordinary skill in the art "to recognize that the [inventor] invented what is claimed," *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), and the enablement requirement by providing a specification that taught one of ordinary skill in the art "how to make and use the invention as broadly as it is claimed," *In re Goodman*, 11 F.3d 1046, 1050, 29 USPQ2d 2010, 2013 (Fed. Cir. 1993) (quoting *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991)). With the '895 patent now expired, Lilly cannot hide behind its once-advantageous broad coverage, disavow its prior compliance with the written description and best mode requirements, and argue that selecting fluoxetine hydrochloride from the class of compounds defined by claim 1 of the '895 patent would not have been obvious.

Having construed claim 1 of the '895 patent and claim 7 of the '549 patent and concluded that the use of fluoxetine hydrochloride is covered by the earlier claim, we must next determine whether there are any differences between the two claims that are ~~patentably distinct.~~ *See Georgia-Pacific*, 195 F.3d at 1327, 52 USPQ2d at 1595; *General Foods*, 972 F.2d at 1279, 23 USPQ2d at 1844. The only discernible difference between claim 1 of the '895 patent and claim 7 of the '549 patent is that the former addresses the treatment of depression in humans while the latter addresses the treatment of serotonin uptake in animals. Humans are a species of the animal genus, and depression is a species ailment of the genus of ailments caused by defective serotonin uptake. Our case law

firmly establishes that a later genus claim is not patentable over an earlier species claim. *See In re Berg*, 140 F.3d 1428, 1437, 46 USPQ2d 1226, 1233 (Fed. Cir. 1998) (affirming the rejection of genus claims in a later patent application for obviousness-type double patenting in light of species claims in an earlier patent); *In re Lonardo*, 119 F.3d 960, 967, 43 USPQ2d 1262, 1267 (Fed. Cir. 1997) (invalidating claims in later patent for obviousness-type double patenting when "many of the alleged differences in elements are in species-genus form," with the earlier patent claiming elements more specifically and the later patent claiming elements more generally); *Goodman*, 11 F.3d at 1053, 29 USPQ2d at 2016; *In re Vogel*, 422 F.2d 438, 442, 164 USPQ 619, 622-23 (CCPA 1970) (affirming a rejection of a claim in a later patent covering a method for packaging meat as obviousness-type double patenting in light of claims in an earlier patent covering a method for packaging pork); *see also Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (reasoning that a later patent "containing a broader claim, more generical [sic] in its character than the specific claim in the prior patent" is void); *Gosteli*, 872 F.2d at 1010, 10 USPQ2d at 1616 (holding that earlier species invention anticipates later generic claim); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claim). Accordingly, we hold that the differences between claim 1 of the '895 patent and claim 7 of the '549 patent are not patentably distinct.

Furthermore, the circumstances giving rise to the present case support our conclusion that claim 7 is invalid for obviousness-type double patenting. This case arose when Barr filed an ANDA application seeking FDA

approval for marketing fluoxetine hydrochloride as an antidepressant, and Lilly responded by suing for infringement of, *inter alia*, claim 7 of the '549 patent. Under the '895 patent, which issued in 1977 and expired in 1994, Lilly possessed the right to exclude others from administering any compound, including fluoxetine hydrochloride, within the class of claimed compounds to treat depression. In effect, under the '895 patent, Lilly had the right to exclude others from engaging in the very conduct for which Barr currently seeks FDA approval. Now, by asserting claim 7 of the '549 patent, Lilly attempts to extend the term of exclusivity it enjoyed under the '895 patent for an additional nine years beyond the statutorily prescribed term. "Effectively extending the patent term, however, is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." *Berg*, 140 F.3d at 1435, 46 USPQ2d at 1232.

IV. CONCLUSION

In sum, because we hold that claim 5 of the '081 patent and claim 7 of the '549 patent comply with the best mode requirement and that claim 7 is invalid for obviousness-type double patenting, we affirm-in-part and reverse-in-part. Also, because we do not reach the issue, we vacate the district court's grant of a jury trial to Barr.

AFFIRMED-IN-PART,
REVERSED-IN-PART, AND VACATED.

COSTS

Each party bears its own costs.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, vs. BARR LABORATORIES, INC., APOTEX, INC., INTERPHARM, INC., BERNARD C. SHERMAN and GENEVA PHARMACEUTICALS, INC., Defendants.	)	IP 96-0491-C-B/S

ENTRY

This matter comes before the Court on the parties' cross-motions for summary judgment as to Defendants' assertion that claim 7 of Plaintiff's United States Patent No. 4,626,549 (the "'549 patent") is invalid for double patenting. For the reasons set forth below, we *deny* Defendants' motion for summary judgment and *grant* Plaintiff's motions for summary judgment as to Defendants' double patenting defense.

BACKGROUND[1]

On April 10, 1996, Plaintiff Eli Lilly and Company ("Lilly") filed this action against Defendant Barr

[1] The factual background of this case is abbreviated here in the interest of efficiency. The relevant facts forming the background of the present litigation have been addressed in several companion entries that are being released at the same

Laboratories, Inc. ("Barr") seeking a declaratory judgment that Barr was infringing two of its patents – U.S. Patent No. 4,314,081 (the "'081 patent") and U.S. Patent No. 4,626,549 (the "'549 patent"). On June 23, 1997, Plaintiff also filed an action against Defendant Geneva Pharmaceuticals, Inc. ("Geneva") seeking a declaratory judgment that Geneva was infringing the same two patents. On September 18, 1997, Lilly filed an Amended Complaint adding ANDA-related counts against additional Defendants Apotex, Inc. ("Apotex") and Bernard C. Sherman ("Sherman"). The actions were consolidated on October 17, 1997.

This patent infringement lawsuit was prompted by the filing of Abbreviated New Drug Applications by Defendants seeking FDA permission to market generic versions of the antidepressant drug Prozac®, which is currently protected by two patents owned by Lilly. The patents at issue, claim 5 of the '081 patent and claim 7 of the '549 patent, are directed to the active ingredient in Prozac®, fluoxetine hydrochloride, and its use to inhibit serotonin uptake in brain neurons.

Several patents are implicated by the parties' motions for summary judgment, including:

> 1) The '549 patent: Claim 7 of the '549 patent deals with a method of blocking the reuptake of the brain chemical serotonin by brain neurons in

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time as this entry, and we hereby incorporate those factual summaries into this entry. The Court will set forth in this entry only those facts necessary to address the issues squarely before the Court regarding the pending motions for summary judgment regarding Defendants' double patenting defense.

animals by administering fluoxetine hydrochloride (the active ingredient in Lilly's Prozac® pharmaceutical).

2) United State Patent No. 4,018,895 (the "'895 patent"): The '895 patent claims a method of treating depression in humans by administering any compound of a broad family of related chemical compounds.

3) United States Patent No. 4,194,009 (the "'009 patent"): The '009 patent claims pharmaceutical dosage forms derived from a broad family of related chemical compounds.

4) United States Patent No. 4,314,081 (the "'081 patent"): Claim 5 of the '081 patent claims the chemical compound fluoxetine hydrochloride.

5) United States Patent No. 4,590,213 (the "'213 patent" or the "Stark patent"): Claim 6 of the Stark patent is directed towards a method of treating anxiety in a human subject in need of such treatment comprised of administering to such human an effective amount of fluoxetine hydrochloride.

6) United States Patent No. 4,329,356 (the "'356 patent" or the "Holland patent"): Claim 13 of the Holland patent is directed towards a method for lowering the blood pressure in hypertensive mammals (mammals with high blood pressure) in need of such treatment comprised of administering to such mammals an anti-hypertensive amount of fluoxetine hydrochloride.

SUMMARY JUDGMENT STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure provides that a motion for summary judgment shall be

granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if there is sufficient evidence for a jury to return a verdict in favor of the nonmoving party on the particular issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510 (1986); *Methodist Med. Center v. American Med. Sec., Inc.*, 38 F.3d 316, 319 (7th Cir. 1994). A disputed fact is material only if it might affect the outcome of the suit in light of the substantive law. *See Anderson*, 477 U.S. at 248, 106 S.Ct. at 2510; *Greenslade v. Chicago Sun-Times, Inc.*, 112 F.3d 853, 857 (7th Cir. 1997). Moreover, "in rendering a decision on a motion for summary judgment, a court must 'view the evidence presented through the prism of the substantive evidentiary burden' that would inhere at trial." *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 880-881 (Fed. Cir. 1998) (quoting *Anderson*, 477 U.S. at 254, 106 S.Ct. at 2513). In considering a summary judgment motion, a court must draw all justifiable inferences in a light most favorable to the opposing party and must resolve any doubt against the moving party. *See Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513; *Spraying Sys. Co. v. Delavan, Inc.*, 975 F.2d 387, 392 (7th Cir. 1992).

While the burden rests squarely on the party moving for summary judgment to show "that there is an absence of evidence to support the nonmoving party's case," *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 2553 (1986), the nonmoving party may not simply rest on the pleadings, but must affirmatively demonstrate by specific

factual allegations that a genuine issue of material fact exists for trial. *See Celotex*, 477 U.S. at 322-23, 106 S.Ct. at 2552-53; *Billups v. Methodist Hosp. of Chicago*, 922 F.2d 1300, 1302 (7th Cir. 1991). Conclusory allegations by a party opposing a motion for summary judgment cannot defeat the motion. *See Smith v. Shawnee Library System*, 60 F.3d 317, 320 (7th Cir. 1995). "The moving party is 'entitled to a judgment as a matter of law' [if] the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex*, 477 U.S. at 323, 106 S.Ct. at 2253. However, if doubts remain as to the existence of a material fact, those doubts should be resolved in favor of the nonmoving party and summary judgment denied. *See Wolf v. City of Fitchburg*, 870 F.2d 1327, 1330 (7th Cir. 1989).

DISCUSSION

"The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof." *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). The Federal Circuit recognizes two different types of double patenting challenges: "same invention" type double patenting and "obviousness-type" double patenting. *See id.; see also General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992).

> "Same invention" double patenting is based upon 35 U.S.C. § 102 (1994), which states that an inventor may obtain "a patent" for an invention. The statute thus permits only one patent to be

> obtained for a single invention, and the phrase "same invention" refers to an invention drawn to substantially identical subject matter. Obviousness-type double patenting, on the other hand, is judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent.

In re Lonardo, 119 F.3d at 965 (citing *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)). *General Foods* sets forth a basic, two-step inquiry for determining double patenting:

> The opinion in In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970), undertook a "restatement of the law of double patenting as enunciated by this court." To summarize it, the opinion says that the first question is: Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. The court was speaking, of course, about the PTO rejection of a pending patent application intended to forestall double patenting. If the rejected claim defines *more* than an obvious variation, it is *patentably distinct.*

972 F.2d at 1278 (emphasis supplied). *General Foods* thus concluded that the appropriate inquiry for determining an obviousness-type double patenting challenge is whether the claimed invention is distinctly patentable. *See id.*

We begin our analysis of the double patenting claim by reminding Barr of the extremely high bar it faces in proving its invalidity defenses. Patents are presumed

valid because they have survived rigorous review by the Patent and Trademark Office (the "PTO") and thus those who challenge the validity of a patent duly issued by the PTO as to arguments the PTO already addressed during the patent prosecution are required to prove the invalidity of such patent by clear and convincing evidence, a high threshold indeed. However, we find in this case that even if the bar were set low for Barr, the evidence it has adduced in support of its double patenting claim would be insufficient to preserve its right to trial on this issue. Barr has not presented evidence allowing us to reach as a matter of deduction the conclusion Barr proposes, nor is the issue one that we are able to determine simply by naked review of the claims of the patents in dispute. Thus, for the reasons set forth below, we are compelled to conclude that Barr has not advanced the necessary factual assertions to survive the entry of summary judgment against it on its double patenting defense.

Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the "scientific explanation" for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion

of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before. In light of this glaring deficiency of Barr's evidentiary record, we *deny* Defendants' motion for summary judgment and *grant* Plaintiff's motions for summary judgment as to Defendants' double patenting defense.

It is so ORDERED this 12th day of January, 1999.

/s/ Sarah Evans Barker
SARAH EVANS BARKER,
CHIEF JUDGE
United States District Court
Southern District of Indiana

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United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ORDER

(Filed Jul. 18, 2001)

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANT, and a response thereto having been invited by the court and filed by the APPELLANT*, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

---

* Barr Laboratories, Inc. filed the response.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on July 25, 2001.

Circuit Judge LINN did not participate in the vote.

FOR THE COURT,

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

Dated: July 18, 2001

cc: Hugh Moore, Richard Clark, James Hurst
Allen Sokal
W. Mentlik, J. Kushan, N. Linck
J. Mueller, J. Vassil, H. Wamsley

ELI LILLY & CO V BARR LABS, 99-1262, -1263, -1264, -1303
(DCT – 96-CV-0491)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

Judgment

ON APPEAL from the U.S. DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA

In CASE NO(S). 97-CV-1029

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED-IN-PART, REVERSED-IN-PART and VACATED.

ENTERED BY ORDER OF THE COURT

DATED MAY 30 2001 /s/ Jan Horbaly lk
Jan Horbaly, Clerk

ISSUED AS A MANDATE: JUL 26 2001

NOTE: Pursuant to Fed. Cir. R. 47.6 this order is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

ON MOTION

Before MAYER, *Chief Judge*, FRIEDMAN, *Senior Circuit Judge*, and GAJARSA, *Circuit Judge*.

ORDER

Eli Lilly and Company (Lilly) moves to stay issuance of the mandate pending the filing of a petition for writ of certiorari at the Supreme Court of the United States. Lilly

advises that the appellants indicate that they will oppose this request.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT,

JUL 26 2001
Date

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Richard S. Clark, Esq.
James F. Hurst, Esq.
Hugh L. Moore, Esq.
Herbert C. Warnsley, Esq.
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Janice M. Mueller, Esq.
Nancy J. Linck, Esq.
Jeffrey P. Kushan, Esq.

FILED
U.S. COURT
OF APPEALS FOR
THE FEDERAL CIRCUIT
JUL 26 2001
JAN HORBALY
CLERK

35 U.S.C. § 100(b)

The term "process" . . . includes a new use of a known process . . . , composition of matter, or material.

---

35 U.S.C. § 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

---

35 U.S.C. § 102

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

. . . .

(g) . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

---

35 U.S.C. § 103

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

. . . .

(c) Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

---

35 U.S.C. § 253

A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

In like manner, any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

Supreme Court, U.S.
FILED
NOV 13 2001
CLERK

No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT BARR LABORATORIES, INC.

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QUESTIONS PRESENTED FOR REVIEW

1. Did the Federal Circuit err by finding double patenting through the straightforward application of 100 years of uniform precedent where Eli Lilly sought and obtained narrower patents for 12 years before requesting an all-encompassing patent monopoly on its basic invention – a monopoly-extending tactic that is no longer possible after a change in the law that Congress enacted in 1995?

2. Did the Federal Circuit err by noting in a footnote that Lilly could not resurrect its invalid patent by filing a post-judgment terminal disclaimer, particularly considering that Lilly had waived the issue by steadfastly refusing to file any such disclaimer throughout six years of litigation over the double-patenting issues?

CORPORATE DISCLOSURE STATEMENT

Respondent, Barr Laboratories, Inc. does not have any parent corporations or any publicly held company that owns 10% or more of the corporation's stock.

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INTRODUCTION

Nothing about the Federal Circuit's decision warrants Supreme Court review. Lilly cites no circuit conflict, no contrary Supreme Court precedent, no issue of national significance, and no constitutional issue. The Federal Circuit itself did not suggest that it was making new law or departing from established precedent in any way. Instead, the court found Lilly's '549 patent invalid for double patenting based on a standard analysis that the courts consistently have applied for over 100 years.

Far from an important issue, Lilly conceded below that its primary question presented has never arisen before and likely will never arise again. Nevertheless, in an attempt to craft an issue meriting Supreme Court review, Lilly does an about-face. It now argues that its primary question presented is significant because the Federal Circuit's decision purportedly will lead to "unhappy results" for our "nation's patent system." (Lilly Pet. at 24). But Lilly earlier told the Federal Circuit that despite "a review of nearly 500 double patenting decisions," it could not find any other case raising the same issue. (Lilly's 2nd Reh'g Pet. at 7). That once-in-a-century issue arose here only because of a confluence of unlikely events, the most significant of which was Lilly's 12-year delay in seeking a patent on what it now describes as its "basic" invention.

Not only did this issue never occur before, but it will never recur in the future. A change in the law prevents the issue from ever arising again. Lilly acknowledged as much below. It told the Federal Circuit that by changing the relevant law in 1995, Congress already "remed[ied]" the double-patenting "problem" that arises from "inordinate delays in the PTO." (Lilly Cross-Appellant Br. at 70). In fact, under the new law, the '549 patent would have expired eight years ago in 1994, thus completely eliminating the monopoly-extending double-patenting issues at the heart of this case.

The Federal Circuit's decision also is unassailable on the merits under long-settled law. To enforce the limited patent monopolies mandated by Congress and the U.S. Constitution, this Court and the appellate courts have held repeatedly that double patenting occurs when an applicant accepts a narrow patent covering a specific member of a class (*i.e.*, a "species" patent) before obtaining a broader patent covering the entire class (*i.e.*, a "genus" patent). That is precisely what happened here. In an effort to obtain an illegitimate monopoly extension through overlapping patents, Lilly first accepted the '213 patent covering a species (the administration of fluoxetine to treat anxiety) and later obtained the '549 patent covering the genus (the administration of fluoxetine for any purpose, including treating anxiety).

Because it does not contest that the '549 patent is invalid under a standard analysis, Lilly is forced to propose a new exception to the double-patenting doctrine that would be limited to the bizarre facts of this specific case – a "prior-art" exception based on a fortuitous public disclosure, which no court has ever before recognized in the doctrine's 100-year history. Lilly asserts that creating such an exception is necessary to address "unfairness" that may result from the delayed issuance of a genus patent. But the courts *already* have created an exception to address any such purported unfairness. That exception is called the "two-way test," which Lilly ignores and which the Federal Circuit correctly held did not apply in this case. Lilly does not even challenge that holding.

Lilly's second question presented – the terminal-disclaimer issue – is equally inappropriate for Supreme Court review. Once again, the issue is unlikely to arise again in the future. Lilly has cited no other case where, for the first time after a final judgment had been entered on appeal, a party attempts to resurrect an invalid patent by filing a terminal disclaimer. Lilly also waived this issue by failing to raise it below. That waiver was intentional; it was a strategic choice designed to obtain the longest possible

patent monopoly. It is too late now for Lilly to raise the issue for the first time in the Supreme Court.

The Federal Circuit also was correct on the merits of this issue. The Federal Circuit noted in a footnote that Lilly could not resurrect the '549 patent with a post-judgment terminal disclaimer, thus preempting any further delay tactics by Lilly. Lilly now asserts that the Federal Circuit's ruling contradicts the applicable statute. But the statute does not even expressly address double patenting. It merely permits patent owners to "disclaim" a portion of their monopoly, but does not state that doing so will avoid a double-patenting violation. *See* 35 U.S.C. § 253 (2001). Indeed, Lilly fails to cite even one case holding that a patent owner may resurrect a patent *already* declared invalid with a post-judgment terminal disclaimer – a result that would violate the long-recognized and deeply-rooted presumption of regularity that attaches to final judgments.

At bottom, Lilly is seeking Supreme Court review of fact-bound issues that never arose before and will never arise again. But certiorari jurisdiction is not designed "merely to give the defeated party . . . another hearing" (*Magnum Imp. Co. v. Coty*, 262 U.S. 159, 163 (1923)), or "for the benefit of the particular litigants" (*Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955)). Thus, this Court should deny Lilly's certiorari petition.

COUNTERSTATEMENT OF THE CASE

I. Factual Background

A. Lilly Intentionally Delayed For 12 Years Before Seeking A Patent On Its Basic Invention.

Lilly filed its first patent application on fluoxetine in 1974. (Lilly App. at 3a). What followed, as the Federal Circuit noted, was "a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy." (*Id.* at 4a). If not for the Federal Circuit's decision, this "Hapsburg legacy" of patents would have resulted in a 26-year monopoly on the use of fluoxetine to treat depression (*id.* at

85a), rather than the 17 years then mandated by the Patent Code. *See* 35 U.S.C. § 154 (1994), *amended by* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4983 (1994). The Federal Circuit noted that this is "precisely the result that the doctrine of obviousness-type double patenting was created to prevent." (Lilly App. at 85a (internal quotation marks omitted)).

Lilly's extended monopoly resulted from a 12-year delay in seeking a patent on its so-called "basic" invention. (*See id.* at 4a). That basic invention was the discovery of fluoxetine's defining biological property – the blocking of uptake in the brain of a chemical known as "serotonin." (*Id.* at 26a). Because serotonin uptake blocking occurs whenever fluoxetine is administered to any patient for any reason, Lilly's '549 patent on that basic invention created a broad monopoly effectively covering *any* pharmaceutical use of the drug, including the treatment of depression and anxiety. (*Id.* at 29a).

Lilly's 12-year delay in requesting a patent on its basic invention was highly unusual. Normally, applicants seek patents on their basic invention *before* seeking patents on later-developed improvement inventions. But Lilly reversed the order here. In 1974, shortly after discovering fluoxetine's biological property, Lilly filed an application seeking a patent with narrow claims to the use of the compound to treat specific diseases. (*Id.* at 3a-4a). Although its 1974 application disclosed that fluoxetine was a serotonin uptake blocker, Lilly did not apply for a patent on that subject. (*Id.*).

During the next 12 years – without requesting a patent on its basic invention – Lilly continued to file applications, present claims, prosecute claims, and obtain patents relating to fluoxetine. (*Id.*). For instance, Lilly's 1974 application included claims covering the chemical compound itself, a sufficient dose of the compound to induce a psychotropic effect, and the use of the compound (and other compounds) to treat depression.

(J.A.00556).[1] These claims resulted in the issuance of three patents between 1977 and 1982. (J.A.00280-290; J.A.00291-300; J.A.00740-749). In 1980, Lilly filed another application claiming the use of fluoxetine to treat hypertension, which resulted in the issuance of another patent in May 1982. (J.A.00304-308). In 1983, Lilly filed yet another application claiming the use of fluoxetine to treat anxiety, which resulted in the issuance of the anxiety patent three years later in 1986. (J.A.00309-313).

Finally, in a March 1986 application – 12 years after its initial patent application – Lilly presented a broad, generic claim directed to fluoxetine's defining biological property. (Lilly App. at 7a-8a; *see also* J.A.00807-808; J.A.00849). The PTO promptly issued the '549 patent on that claim in December 1986. (Lilly App. at 7a). Contrary to Lilly's unsupported representation, Lilly's "broad, basic application" on serotonin blocking did not encounter any "examination complexities" that delayed issuance. (Lilly Pet. at 9). From beginning to end, the prosecution lasted only nine months from March 1986 to December 1986, which was markedly shorter than the typical multi-year patent prosecution. The "examination complexities" recounted in Lilly's petition all occurred *before* Lilly applied for the '549 patent in March 1986.

B. By Delaying For 12 Years, Lilly Sought To Artificially Extend The Monopolies Granted Through Earlier-Issued Fluoxetine Patents.

If not for the Federal Circuit's decision, Lilly's delaying tactic would have resulted in an extension of Lilly's monopoly rights under all of its earlier-issued fluoxetine patents. Before that decision, the '549 patent was scheduled to expire in December 2003, which was later than the scheduled expirations of Lilly's five other fluoxetine patents:

---

1. References to "J.A.__" refer to the parties' joint appendix filed with the Federal Circuit on October 14, 1999.

Patent	Scheduled Expiration
depression	April 1994
psychotropic effect	April 1994
hypertension	October 2000
fluoxetine	February 2001
anxiety	May 2003
serotonin blocking	December 2003

(J.A.00291; J.A.00740; J.A.00280; J.A.00304; J.A.00312; J.A.00320). The '549 patent effectively extended all of the earlier patent terms because, as the Federal Circuit held in a now-uncontested factual ruling, serotonin blocking occurs whenever fluoxetine is administered to any patient for any reason. (Lilly App. at 29a). For instance, even though Lilly's depression patent expired in 1994, Lilly argued that the '549 patent precluded Barr from selling fluoxetine as an antidepressant until December 2003. If that argument were accepted, Lilly would have expanded its monopoly over the use of fluoxetine to treat depression to 26 years. (*See id.* at 85a). And even after the Federal Circuit's decision, contrary to Lilly's current cries of inequity, Lilly has enjoyed an unduly extended depression monopoly – 23 years instead of 26 years – still 6 years more than the then Congressionally-mandated term. 35 U.S.C. § 154 (1994).

Except to obtain its extended monopoly, there was no reason for Lilly to wait 12 years before requesting a patent on its basic invention. Lilly attempts to explain the 12-year delay by implying that it was distracted by difficulties prosecuting other patent applications. But this excuse is mere makeweight. Parties routinely prosecute multiple patent applications at the same time, and in fact, Lilly did so in this case. During the early 1980s,

Lilly was prosecuting simultaneously at least *five* fluoxetine-related patent applications. (J.A.00280-90; J.A.00291-300; J.A.00740-49; J.A.00320-30; J.A.01069-73; J.A.01387-92). As the Federal Circuit correctly recognized, nothing prevented Lilly from seeking the '549 patent long before 1986. (Lilly App. at 24a n.7).

C. Even After Delaying For 12 Years, Lilly Still Could Have Avoided A Double-Patenting Violation By Filing A Timely Terminal Disclaimer, But It Chose Not To Do So.

Even after delaying the issuance of the '549 patent for 12 years, Lilly still could have avoided the patent's invalidity by filing an appropriate terminal disclaimer before the PTO issued the patent. A terminal disclaimer officially abandons the monopoly-extending portion of the later-issued patent and, thus, avoids double-patenting issues. Lilly chose not to do so here. In fact, Lilly did not offer to file a terminal disclaimer even during six years of double-patenting litigation before the district court and the Federal Circuit.

Instead, Lilly proposes filing a terminal disclaimer for the first time in its certiorari petition before this Court. Even though the matter was directly at issue below – *i.e.*, whether the '549 patent was invalid – Lilly never argued that a post-issuance, post-litigation terminal disclaimer could avoid the patent's invalidity. Instead, Lilly made a strategic decision not to file a terminal disclaimer before now. In an effort to preserve the longest possible monopoly, Lilly chose not to abandon any portion of its monopoly with a terminal disclaimer. Having pursued that strategy and lost, Lilly cannot now, after the Federal Circuit has ruled, raise a terminal-disclaimer issue for the first time in the Supreme Court. It is simply too late.

II. Proceedings Below

A. After An Unusually Thorough Review By The *En Banc* Court, A Unanimous Panel Of The Federal Circuit Held The '549 Patent Invalid For Double Patenting Under "Firmly Establishe[d]" Law.

The Federal Circuit reached its decision in this case after an unusually thorough review of the issues. Ten active judges on the Federal Circuit reviewed the underlying double-patenting issues a total of three times. And with only one possible exception – which is debatable because the Federal Circuit denied Lilly's final rehearing petition with no dissent – no judge has questioned the conclusion that the '549 patent is invalid.

Throughout this litigation, Barr has contended that the '549 patent was invalid for double patenting over each of Lilly's five earlier-expiring fluoxetine patents. In August 2000, the Federal Circuit declared the patent invalid over Lilly's depression patent, which had expired in 1994. The court found that the '549 patent represented an effort by Lilly to "extend the term of exclusivity it enjoyed under [its depression] patent for an additional nine years beyond the statutorily prescribed term." (Lilly App. at 85a).

In response to that decision, Lilly filed a petition for rehearing *en banc*, arguing that there was at least a factual issue over whether the '549 patent was invalid over the depression patent. (*See* Lilly's 1st Reh'g Pet. at 4-7). In addition to its lack of merit, Lilly's purported factual dispute was inconsequential. The panel's reasoning applied with equal force to Lilly's anxiety and hypertension patents, neither of which required the Federal Circuit to wade into any evidentiary issues. Thus, in its opposition to Lilly's petition, Barr suggested that the Federal Circuit avoid Lilly's purported factual dispute by applying the panel's reasoning to either the anxiety or hypertension patent. (*See* Barr's Opp'n to Lilly's 1st Reh'g Pet. at 2).

The Federal Circuit did precisely that. The *en banc* court "vacated the panel's original opinion," and then "reassigned the opinion to the panel for a specific revision of the double patenting section." (Lilly App. at 2a). The panel made that "specific revision" by again holding the '549 patent invalid for double patenting, but this time over the anxiety patent as Barr had suggested. When declaring the later-issued '549 patent invalid over the earlier-issued anxiety patent, the panel stated that "[o]ur case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." (*Id.* at 31a). Before public issuance, the *en banc* court *sua sponte* reviewed the panel's revised opinion. (*Id.* at 2a). Only one judge dissented from among ten active judges – Judge Newman – and she did so in a written opinion that no other judge joined.

In response to the Federal Circuit's second opinion, Lilly filed another petition for rehearing *en banc*, which gave the *en banc* court a third opportunity to review the panel's reasoning. This time, however, Lilly took its cue from Judge Newman by fully developing a statutory prior-art argument that Lilly had earlier raised only in passing. Lilly expanded its earlier one-paragraph analysis of this issue (*see* Lilly Cross-Appellant Br. at 62) into 15 pages of new arguments about the case law and previously uncited legislative history and published PTO policies (*see* Lilly's 2nd Reh'g Pet.). At the Federal Circuit's invitation, Barr filed an opposition fully explaining why Lilly's novel prior-art argument was logically and legally flawed. The Federal Circuit then denied Lilly's second rehearing petition. Notably, after Barr filed its opposition brief, Judge Newman did not renew her dissent. (*See* Lilly App. at 95a-96a). Thus, the denial was unanimous. (*Id.*).

B. In Its Zeal To Resurrect Its Most Important Patent, Lilly Distorts The Record.

In its zeal to resurrect a patent monopoly allegedly worth "$4 billion in sales" (Lilly Pet. at 2), Lilly distorts the record in

three specific ways. First, Lilly not only fails to acknowledge that Judge Newman did not ultimately maintain her dissent, but it also misstates her original dissent. Judge Newman divided her initial dissent into two separate sections, one addressing the prior-art issue now before this Court and the other addressing an "inherency" issue not before the Court. (Lilly App. at 43a-50a). Lilly, unfortunately, quotes from Judge Newman's *inherency* discussion to suggest that the *prior-art* issue is important. (Lilly Pet. at 24).

Second, to imply misleadingly that the disputed issues are somehow important, Lilly refers to the *amicus* support it received in the Federal Circuit. Lilly mentions that "[f]ive *amici*, including the Federal Circuit's own bar association, sought to file briefs supporting Lilly's petition for rehearing of the second opinion." (*Id.* at 12). But Lilly neglects to mention that none of those *amici* focused on Lilly's prior-art argument. They focused on other issues, such as the standard for determining whether to apply a "one-way" or "two-way" double-patenting analysis, an issue not before this Court. In fact, other than Lilly itself, no party has yet shown any interest in the prior-art issue.[2]

Third, to support the notion that the Federal Circuit "was not receptive to suggestions of continued error in its second opinion," Lilly notes that the court declined to accept any of the five proposed *amicus* briefs. (*Id.*). Lilly is telling only half the story. Far from not carefully considering the issues, the Federal Circuit rejected those five *amicus* briefs only because of earlier events that Lilly fails to recite. Since the Federal Circuit's original decision in August 2000, Lilly has made substantial

2. Barr understands, however, that certain parties soon will be filing or seeking leave to file *amicus* briefs in this Court on the prior-art issue – including two organizations that included Lilly as a prominent member called "Intellectual Property Owners Association" and "Biotechnology Industry Organization" (both of which are now seeking leave to file their third *amicus* brief supporting Lilly on yet a third different issue) and five law professors (at least two of whom were formerly employed by law firms that have represented Lilly in this case).

efforts to generate *amicus* support in favor of whatever argument it was then pursuing. Even though Lilly's two rehearing petitions addressed completely different issues, some Lilly-solicited *amici* sought leave to file briefs supporting *both* petitions. The Federal Circuit accepted the *amicus* briefs on the first petition, but only after noting that they were "at the very borderline of denial for leave of filing" because they were "for the most part repetitive of the arguments made by the parties." *Eli Lilly & Co. v. Barr Labs., Inc.*, Nos. 99-1262, 99-1263, 99-1264, 99-1303 (Fed. Cir. Feb. 14, 2001). When Lilly and its allies tried the same tactic again for Lilly's second petition, the Federal Circuit rejected the unhelpful filings.

REASONS FOR DENYING THE WRIT

I. Lilly's Prior-Art Issue Is Not Important.

Lilly's prior-art issue does not warrant Supreme Court review. As this Court has long recognized, "certiorari jurisdiction is designed to serve purposes broader than the correction of error in particular cases . . . ." *Watt v. Alaska*, 451 U.S. 259, 275 n.5 (1981) (Stevens, J., concurring). This Court does not "grant a certiorari to review evidence and discuss specific facts." *United States v. Johnston*, 268 U.S. 220, 227 (1925). Lilly's argument, however, presents a fact-bound issue that never arose before in the 100-year history of double-patenting jurisprudence and likely will never arise again due to a statutory change in the law.

A. Lilly's Prior-Art Issue Never Arose Before.

Far from asserting that its prior-art issue was important to the patent system, Lilly told the Federal Circuit that even after "a review of nearly 500 double patenting decisions," it could not locate even one other case where the issue arose, much less a case that recognized its proposed prior-art exception. (Lilly's 2nd Reh'g Pet. at 7).

This is not surprising because in most cases, unlike here, applicants seek patents on their basic inventions *before* obtaining patents on later-developed improvements, thus avoiding double-patenting problems. And even when unusual delays result in the issuance of the improvement patent first, a prior-art issue normally would never surface because of the lack of any relevant public disclosure. Such disclosures are unlikely because, for the improvement patent to issue first, the patent owner normally would need to request the improvement patent at the same time or at least soon after requesting the basic patent. As a practical matter, the lack of any significant lag between the two requests prevents interim public disclosures.

Here, the prior-art issue arose only because of Lilly's strategic 12-year delay in seeking a patent on its basic invention. Lilly filed an application that disclosed its purported basic invention in 1974, but failed to request a patent on the invention until 1986. (Lilly App. at 4a, 7a-8a and 24a n.7). During that 12-year delay, Lilly sought related patents through other applications containing identical text, which resulted in the public disclosure of Lilly's basic invention when the PTO issued Lilly's depression patent in 1977. (J.A.00291-300). Lilly's continued delay after 1977 then enabled it to develop its anxiety invention, request an anxiety patent in 1983, and obtain the anxiety patent all before obtaining a patent on a basic invention it developed 12 years earlier. (J.A.00312-313; J.A.00320-330). Any change in that sequence of events would have avoided the prior-art issue altogether.

Barr's exhaustive research confirms the rarity of Lilly's prior-art issue. After reviewing virtually every double-patenting decision since 1894, Barr located only one other case where one patented invention was "statutory prior art" to the other. *See In re Borg*, 392 F.2d 642, 643 (C.C.P.A. 1968). In that case, contrary to Lilly's argument, the Court of Customs and Patent Appeals recognized that double patenting existed (curable only through a terminal disclaimer filed before the patent's issuance)

even though one claimed invention "seemingly enjoy[ed] the status of statutory prior art" to the other. *Id.* The patent owner, however, never asserted any purported prior-art exception and, thus, the court never addressed the issue.

B. Lilly's Prior-Art Issue Likely Will Never Arise Again.

A 1995 change in the law makes it exceedingly unlikely that Lilly's prior-art issue will ever arise again. Before 1995, a patent's 17-year term was measured from the date of its issuance. This created fertile ground for double-patenting issues, particularly when an applicant delayed the issuance of its basic patent, which effectively could extend the term of any earlier-issued improvement patent. Under the new law, however, patents have 20-year terms measured from the earliest application that the patentee relies on for a priority date. *See* 35 U.S.C. § 154 (2001); *Abbott Labs v. Novopharm Ltd.*, 104 F.3d 1305, 1308 (Fed. Cir. 1997). By tying the patent's expiration date to the earliest priority date, the statute prevents patent owners from using post-application delay and later expiration dates to obtain monopoly extensions. Here, for example, the '549 patent would have expired in 1994 under the new law because Lilly relied on the original 1974 application for the patent's priority date.

As Lilly has recognized, the new law prevents its prior-art issue from arising again. When arguing against a standard double-patenting analysis (called the "one-way test"), Lilly acknowledged below that the new law already "remed[ied]" the problems arising from "inordinate delays in the PTO":

> A better alternative to a one-way test for remedying this problem would be legislation dealing with the consequences of inordinate delays in the PTO. That, of course, has now happened, through legislative enactment of the 20-year term from the effective filing date rather than 17 years from the date of issue. 35 U.S.C. § 154 (1998).

(Lilly Cross-Appellant Br. at 70). This change in the law, by itself, warrants the denial of Lilly's petition for certiorari. *See Morris v. Weinberger*, 410 U.S. 422 (1973) (dismissing writ of certiorari as improvidently granted where Congress amended disputed statutory provisions); *Rice*, 349 U.S. at 73-80 (dismissing writ of certiorari as improvidently granted after learning of corrective legislation that "bars the ultimate question presented in this case from again arising"); *Dist. of Columbia v. Sweeney*, 310 U.S. 631 (1940) (denying certiorari "in view of the fact that the tax is laid under a statute which has been repealed and the question is therefore not of public importance"); Robert L. Stern, *Denial of Certiorari Despite A Conflict*, 66 Harv. L. Rev. 465, 470 (1953) (noting that even a clear circuit conflict "will not necessarily result in the granting of certiorari if the issue is no longer a live one," such as when "the statute upon which the controversy rested ha[s] expired or been amended in a manner which would prevent the problem from arising in the future").

This new legislation also refutes Lilly's suggestion that the "Federal Circuit's decision undermines the very spirit of innovation that is the touchstone of patent law." (Lilly Pet. at 25). Lilly is speculating that future applicants will delay seeking improvement patents until after their basic patents issue to avoid the risk of double patenting. (*Id.* at 26). According to Lilly, applicants will be concerned about the possibility of "substantial delay in the issuance of a patent on a groundbreaking basic invention," which Lilly asserts will create double-patenting problems in the event the improvement patent issues first. (*Id.*). But that purported concern is not relevant as of 1995 – patent monopolies are no longer measured from the date of the "issuance of a patent" and, therefore, "substantial delay[s]" before issuance cannot possibly create any double-patenting issues. Consequently, contrary to Lilly's argument, the Federal Circuit decision's does not create a reason to delay the request for an improvement patent.

C. Lilly's Prior-Art Issue Is Not Even Important To The Outcome Of *This* Case.

Lilly's prior-art argument will not even change the outcome of *this* case and, thus, is wholly unimportant. Barr argued below that the '549 patent was invalid over each of Lilly's five earlier-expiring fluoxetine patents. The Federal Circuit held the '549 patent invalid over the anxiety patent alone and, thus, never reached the other four patents. Of those four patents, Lilly's prior-art argument applies only to Lilly's hypertension patent. Thus, even if the argument had any merit, the '549 patent would remain invalid over the remaining three patents.

In sum, Supreme Court review is not warranted for a fact-bound double-patenting issue that Lilly argues never arose before and that, based on a 1995 change in the law, likely will never arise again, particularly considering that the issue will not even impact the validity of Lilly's own patent.

II. The Federal Circuit Correctly Rejected Lilly's Prior-Art Argument.

Lilly ultimately is seeking mere error correction from this Court, which is not the function of certiorari jurisdiction. In any event, there is no error to correct because the Federal Circuit properly rejected Lilly's prior-art argument. Stripped of all of its rhetoric, Lilly is arguing that the Federal Circuit's decision will adversely impact the patent system based on the notion that the court somehow changed the law. But the Federal Circuit itself did not suggest it was changing the law in any way. Instead, as demonstrated below, the court correctly applied a straightforward rule in the very same way the rule has been applied since 1894.

A. Far From Contradicting The Statutory Regime, The Federal Circuit's Decision Was Compelled By The Statutory Limit On Patent Terms.

The Federal Circuit relied on 100 years of uniform case law to find the '549 patent invalid for double patenting. (Lilly App. at 22a-32a). Lilly argues that the court nevertheless erred because its decision purportedly "contradicts the statutory regime for determining separate patentability." (Lilly Pet. at 12). Lilly contends that because its anxiety invention was purportedly patentable over the '549 invention under Section 103 of the Patent Code, which requires non-obviousness over the statutory prior art, the '549 patent is immune from a standard double-patenting analysis.

But a Section 103 analysis and a double-patenting analysis are separate and independent. Section 103 sets forth only one of *many* independent requirements for obtaining a patent. As the patent statute explains, a party who invents a "new and useful process . . . may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2001). In addition to Section 103, one such "condition and requirement" is compliance with the statutory and constitutional limit on the term of a patent monopoly, which is what mandates the rule against double patenting. *See* U.S. Const., art. I, § 8, cl. 8 (recognizing that Congress shall have the power "[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing *for limited [t]imes* to . . . [i]nventors the exclusive [r]ight to their . . . [d]iscoveries") (emphasis added); 35 U.S.C. § 154 (1994) (setting specific limits on the term of a patent monopoly).

Because they are separate and independent requirements, Lilly's effort to manufacture a "conflict" between a Section 103 analysis and a double-patenting analysis is illogical. Section 103 and the double-patenting doctrine have "distinct and separate" purposes, thus "requiring different inquiries and representing mutually exclusive grounds for rejecting claims." *In re Bowers*, 359 F.2d 886, 889 (C.C.P.A. 1966). Along with

Section 102, Section 103 determines whether the claimed invention is patentable over the statutory prior art. The double-patenting doctrine, on the other hand, determines whether the applicant is improperly extending its patent monopoly beyond the statutorily-prescribed term. It embodies the longstanding conclusion that – regardless of whether the claimed invention is unobvious over the statutory prior art – applicants cannot use their control over patent prosecution to obtain an extended monopoly. *See Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 201 (1894); *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993); *In re Blattner*, 245 F.2d 491, 494 (C.C.P.A. 1957).

B. To Enforce The Statutory Limit On Patent Terms, The Federal Circuit Applied A Century-Old Double-Patenting Rule In A Straightforward Way.

Far from contradicting the "statutory regime," the Federal Circuit's decision applied a standard double-patenting rule that has remained undisturbed since 1894. Over a century ago in *Miller*, this Court held that, when obtained by the same applicant, a "second patent . . . containing a broader claim, more generical in its character, than the specific claims, contained in [a] prior patent, is . . . void." 151 U.S. at 198. That rule exists, according to this Court, because otherwise the "new and later patent . . . would operate to extend or prolong the monopoly beyond the period allowed by law." *Id.* at 198 (citing *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819)).

In the century since *Miller*, courts continuously have enforced the statutory limits on patent monopolies by applying the same rule, which is "[p]erhaps the most frequently cited statement of the rule" against double patenting. *Pierce v. Allen B. Du Mont Labs., Inc.*, 297 F.2d 323, 327 (3d Cir. 1961). In 1957, the Court of Customs and Patent Appeals surveyed the controlling authority and confirmed that "an applicant who accepts a patent containing only claims which are limited to a single species cannot thereafter obtain a second patent containing

claims generic to that species." *Blattner*, 245 F.2d at 494. The court explained that this "sound" rule enforces the statutory limits on patent monopolies:

> [W]ithholding of the presentation of generic claims in one application until after a patent has been issued on another application containing claims limited to a species of the genus would make some extension of monopoly inevitable, and a very considerable extension probable if a second patent containing generic claims, were granted.

Id.

As recently as 1993, the Federal Circuit again cited *Miller* when confirming the long-settled law: "A second application – 'containing a broader claim, more generical in its character than the specific claim in the prior patent' – typically cannot support an independent valid patent." *Goodman*, 11 F.3d at 1053 (quoting *Miller*). The Federal Circuit explained that allowing an applicant to obtain the broader claim under such circumstances "would extend the exclusionary right past the 17-year limit mandated by Congress" in violation of "Supreme Court precedent." *Id.*; *accord James v. Campbell*, 104 U.S. 356, 382 (1881) ("It is hardly necessary to remark that the patentee could not include in a subsequent patent any invention embraced or described in a prior one granted to himself. . . ."); *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998) (holding "all of the genus claims" invalid based on double patenting over earlier-patented "species claims"); *In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982) (recognizing case as "genus-species relation" and holding "generic" claims invalid based on double patenting over earlier patented "specific" claims).

Here, the Federal Circuit applied the century-old *Miller* rule in a straightforward way. Lilly first accepted a species patent (the anxiety patent) and later accepted a genus patent (the '549

patent). As the Federal Circuit correctly recognized, this is a classic example of double patenting. (Lilly App. at 22a–32a).

C. The Courts Have Already Addressed Lilly's "Unfairness" Concerns With A Double-Patenting Exception Called The "Two-Way Test," Which Lilly Ignores And Which Does Not Apply Here.

Because it does not dispute that the '549 patent is invalid under *Miller*, Lilly is forced to ask this Court to create a brand-new exception to the century-old *Miller* rule. Lilly contends that this proposed exception – the prior-art exception – is necessary to avoid unfairness when there is a "substantial delay in the issuance of a patent on a groundbreaking invention," which may cause an applicant's later-filed improvement or species patent to issue first. (Lilly Pet. at 26).

But there is no need to create a *new* exception to address this concern because such an exception *already exists* – the "two-way test." Courts normally apply a one-way double-patenting analysis, where the only relevant inquiry is whether the later-issued patent (here, the '549 patent) is patentable over the earlier-issued patent (here, the anxiety patent). The two-way test is a "narrow exception" to that standard analysis, under which courts also consider the reverse inquiry by asking whether the *earlier-issued* patent is patentably distinct from the *later-issued* patent. *Berg*, 140 F.3d at 1432.

But the two-way exception applies only in the "special circumstances" when the PTO – not the applicant – delays the issuance of a basic patent. *Id.* It is designed "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *Id.*; *accord In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997) (two-way exception does not apply because applicant "had significant control" over when the applications would be filed and "orchestrated the rate of

prosecution"); *Goodman*, 11 F.3d at 1053 (two-way exception does not apply because "PTO actions did not dictate the rate of prosecution" and applicant "chose to file a continuation and seek early issuance of the narrow species claims"); *In re Braat*, 937 F.2d 589, 593-94 (Fed. Cir. 1991) (applying two-way exception only because the applicant did not have "complete control" over "the rate of progress of the applications through the PTO" and finding that it was "not [the applicant's] fault that the [more specific] claims . . . issued first").

Thus, an exception already exists to protect patent owners from double patenting when the delay is not their fault. The Federal Circuit correctly held, however, that this exception does not apply here because Lilly – not the PTO – was responsible for delaying the '549 patent's issuance. (Lilly App. at 24a n.7). When an applicant exercises control over the order in which its patents issue, the courts consistently have declined to apply the two-way exception. In *Berg*, for instance, the Federal Circuit explained that the two-way exception does not apply "under settled case law" when an applicant files "genus claims long after the species claims even though the two were invented at nearly the same time or the genus claims were invented first . . ." 140 F.3d at 1434 n.6. Here, Lilly did exactly that, filing its "genus claim[ ]" to serotonin blocking three years after its "species claim" to anxiety treatment, "even though . . . the genus claim[ ] [was] invented first." Thus, Lilly exercised complete control over the order of patent issuance, which precludes the two-way exception. *See* 3 Donald S. Chisum, *Chisum on Patents* § 9.03[2][c] (2001) (the two-way exception does not apply when "the later issuing generic claim [was] filed after the application" containing the species).

Even though its certiorari petition does not mention the two-way exception, much less argue that it applies, Lilly relies heavily on one of the earliest examples of that exception – *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712 (6th Cir. 1897). (*See* Lilly Pet. at 15-17). In *Ohio Brass*, the applicant

applied for its basic patent "more than a year before" applying for its improvement patent. 80 F. at 724. The PTO nevertheless issued the patents in the reverse order, with the improvement patent issuing before the basic patent. *Id.* The Sixth Circuit thus declined to find double patenting, noting that this was a case "where the delay in issuing of the patent for the main invention cannot be charged to the laches . . . of the patentee . . . ." *Id.* Here, in contrast, the delay in issuing the patent for the main invention *can* be charged to Lilly, which precludes application of the two-way exception under *Ohio Brass's* reasoning.

Lilly nevertheless argues that the Federal Circuit should not have considered Lilly's delay because Barr did not assert a laches defense. (Lilly Pet. at 23). But regardless of whether Barr asserted a laches defense, Lilly's delay was indisputably relevant to the Federal Circuit's rejection of the two-way exception – an issue that Lilly self-consciously ignores. Lilly similarly asserts that the Federal Circuit erred because its *earlier-issued* anxiety patent was allegedly patentable over its *later-issued* basic patent. But this backwards analysis is relevant *only* under the two-way exception. Because it does not contend that the two-way exception applies, Lilly's argument is manifestly irrelevant under a century of settled law.

D. There Is No Rational Justification For Lilly's Proposed Prior-Art Exception, Which Contradicts The Purpose Of The Rule Against Double Patenting.

Finally, Lilly's proposed prior-art exception would defeat the purpose of the rule against double patenting. Whether or not its subject matter is prior art to the species patent, a later-issued genus patent still would "operate to extend or prolong the [earlier species] monopoly beyond the period allowed by law." *Miller*, 151 U.S. at 198 (citing *Odiorne*). And "[e]ffectively extending the patent term . . . is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." *Berg*, 140 F.3d at 1435. While an exception to the

double-patenting doctrine makes sense when the PTO is to blame for the extended monopoly – hence, the two-way exception – there is no good reason for permitting such extensions when the patentee is responsible.

In fact, Lilly's proposed exception affirmatively would encourage monopoly extensions. This case proves the point. Once its genus invention became prior art to the anxiety and hypertension patents – thus avoiding double patenting under the proposed exception – Lilly could have delayed its genus patent's issuance with impunity. Indeed, it could have delayed the '549 patent's issuance until just before the anxiety patent expired, thereby obtaining 34 years of species' exclusivity. Thus, adopting Lilly's prior-art exception would make the rule against double patenting a dead letter and directly undercut the thrust of the limited terms of patents mandated by Congress.

The lack of any policy justification for a new prior-art exception is confirmed by the extraordinary breadth of Lilly's arguments, which, if accepted, would logically require this Court to overrule the double-patenting doctrine. Lilly contends that it constitutes unfair "discriminat[ion] against the owner of the basic patent" to invalidate the '549 patent over the anxiety patent because, if they were owned by separate parties, both patents might have been valid. (Lilly Pet. at 24-25). But that is almost *always* the case in double patenting. In every case where a later-issued genus patent is invalid for double patenting over an earlier-issued species patent, the two patents could be valid if separately owned. This only makes sense. Double patenting prevents a *single applicant* from obtaining an extended patent term through its control over patent prosecution – an issue that does not exist when the applications are separately owned. *See Miller*, 151 U.S. at 198; *Berg*, 140 F.3d at 1434 n.6; *Goodman*, 11 F.3d at 1053; *Blattner*, 245 F.2d at 494.

Lilly similarly argues – repeatedly and without citation – that the Federal Circuit erred by focusing "on the order in which the . . . *patents issued*" rather than "on the order in which the

two *inventions were discovered.*" (*See, e.g.*, Lilly Pet. at 5 (emphasis in original)). If that were error, courts have been committing the same error every time they found double patenting for the last 100 years. Double patenting *always* focuses on patent issuance dates because the doctrine is designed to prevent undue monopoly extensions, a question that was determined by patent issuance dates before the change in the law in 1995. *See, e.g.*, *Berg*, 140 F.3d at 1437 (conducting double-patenting analysis by focusing on the order the patents issued); *Goodman*, 11 F.3d at 1053 (same); *Blattner*, 245 F.2d at 494 (same).

In addition to generalized attacks that apply broadly to the entire double-patenting doctrine, Lilly attempts to justify its proposed exception with tortured logic that cannot withstand even mild scrutiny. Lilly contends that the rule against double patenting cannot "intrude into [an] area where Congress has supplied the complete test for separate patentability in the statutory scheme of Title 35." (Lilly Pet. at 19). But Title 35 does *not* supply the "complete test" for the *relevant* inquiry. Lilly argues that a public disclosure made Section 103 applicable to determining whether the *earlier-issued* anxiety patent was patentably distinct from the *later-issued* '549 patent. But that inquiry is relevant only under the inapplicable two-way test. No public disclosure made Section 103 relevant to the proper inquiry under the one-way test, *i.e.*, whether the *later-issued* '549 patent was patentably distinct from the *earlier-issued* anxiety patent. Thus, even under Lilly's own illogical argument, the double-patenting doctrine applies in this case.

In the end, Lilly argues that the Federal Circuit changed the law only by ignoring a double-patenting rule that has remained undisturbed since 1894. The Federal Circuit merely applied that century-old rule in a straightforward way. As always, even without a terminal disclaimer, a later-issued genus patent will be valid over an earlier-issued species patent as long as the applicant, unlike here, files the genus claims first and is not responsible for reversing the order of patent issuance.

III. The Terminal-Disclaimer Issue Does Not Merit Supreme Court Review.

A. Not Even Lilly Contends That The Terminal-Disclaimer Issue Satisfies Any Of The Traditional Bases For Supreme Court Review.

Nothing about Lilly's second question presented – the terminal-disclaimer issue – merits Supreme Court review. Not even Lilly itself asserts that the question satisfies any of the traditional bases for Supreme Court review. It cites no circuit conflict, no contrary Supreme Court precedent, and no constitutional issue. Indeed, Lilly never even asserts that the issue is somehow important to anyone other than the litigants in this case. As evidenced by the fact that it addressed the issue in a mere footnote, the Federal Circuit certainly did not consider the issue important. This lack of importance is confirmed by Lilly's failure – despite purportedly reviewing nearly 500 double-patenting decisions – to cite even one other case addressing whether a post-judgment terminal disclaimer could resurrect an invalid patent.

B. Lilly Waived Its Terminal-Disclaimer Argument, Which Is Rife With Never-Litigated Factual Issues, By Intentionally Declining To Raise It Before The Federal Circuit.

Supreme Court review also is inappropriate because Lilly waived its terminal-disclaimer argument. During six years of litigation, Lilly never attempted to file a terminal disclaimer, not even when filing its last petition for rehearing and not even on a contingent basis. The Federal Circuit merely addressed this issue *sua sponte* in a footnote. When an appellate court *sua sponte* addresses an issue the petitioner never raised, this Court typically will exercise its certiorari jurisdiction only "where the issue is . . . in a state of evolving definition and uncertainty and one of importance to the administration of federal law." *See Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1099 n.8 (1991)

(citations and internal quotation marks omitted); *accord E.E.O.C. v. F.L.R.A.*, 476 U.S. 19, 24 (1986) ("Our normal practice, from which we see no reason to depart on this occasion, is to refrain from addressing issues not raised in the Court of Appeals."). Lilly makes no effort to make any such showing, which it cannot do because this is the first and only case to ever address the issue.

Undeveloped factual issues also counsel against Supreme Court review. Because Lilly is raising the terminal-disclaimer issue for the first time in the Supreme Court, the parties never developed a record on the issue below. Possible factual issues abound, including, for instance, issues relating to the doctrine of equitable estoppel, which would preclude Lilly's belated effort to file a terminal disclaimer. Under that fact-intensive doctrine, the delayed assertion of an alleged property right is barred upon proof of misleading conduct, action taken in reliance on that conduct, and resulting prejudice. *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 59 (1984); *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1557 (Fed. Cir. 1996).

Here, Barr argued for six years that the '549 patent was invalid for double patenting and during that whole time, Lilly never filed a terminal disclaimer. (*See* Lilly Pet. at 28). That was a strategic decision. In fact, Lilly did the exact opposite – it sought to *preserve* its extended monopoly by disclaiming the earlier-expiring anxiety and hypertension patents. Thus, along with the rest of the pharmaceutical industry, Barr reasonably concluded that Lilly did not intend to file a terminal disclaimer. As a result – after the Federal Circuit's decision, but before Lilly proposed filing a terminal disclaimer – Barr sold over $200 million of generic fluoxetine and, therefore, would be prejudiced severely if Lilly now were permitted to make new arguments about the validity of the '549 patent. Because Lilly never raised the issue below, there is no evidentiary record whatsoever on this fact-intensive equitable defense. This alone

warrants the denial of Lilly's certiorari petition. *See Mishkin v. New York*, 383 U.S. 502, 512-13 (1966) (dismissing certiorari as improvidently granted where there was "neither evidence nor findings" on relevant underlying issues and, thus, the issues were "not presented by the record with sufficient clarity to require or justify their decision").

Denial additionally is warranted because the terminal-disclaimer issue is not yet ripe for judicial review. Nothing in the record indicates that Lilly *already* has filed a terminal disclaimer. Lilly's petition does not represent that it has done so and, instead, indicates only that it is willing to do so. (Lilly Pet. at 27-28). Until it files such a terminal disclaimer with the PTO, however, Lilly's terminal-disclaimer argument is not ripe for adjudication. Certiorari jurisdiction is not designed for this Court to render advisory opinions about the legal effect of an action that a litigant may or may not decide to take in the future. "It has long been this Court's considered practice not to decide abstract, hypothetical or contingent questions . . . ." *United Pub. Workers of Am. v. Mitchell*, 330 U.S. 75, 90 n.22 (1947) (internal quotation marks omitted). Thus, were this Court "to pass upon the purely artificial and hypothetical issue tendered" by Lilly's petition, it would "not only in effect be rendering an advisory opinion but also lending [itself] to an unjustifiable intrusion upon the time of this Court." *Conway v. Cal. Adult Auth.*, 396 U.S. 107, 110 (1969).

C. Lilly's Terminal-Disclaimer Argument Is Not Even Important To The Outcome Of *This* Case.

In addition to its lack of general importance, the terminal-disclaimer issue is not even important to the outcome of *this* case. Lilly seeks to disclaim the portion of the '549 patent term extending beyond May 2003, which was the scheduled expiration date for Lilly's anxiety patent. But even if Lilly were permitted to do so, the '549 patent would remain invalid over

its hypertension patent, which already expired in 2000. (J.A.00304-308; Lilly Pet. at 28 n.10). In fact, Lilly told the Federal Circuit that the anxiety and hypertension patents present "virtually the identical" double-patenting issues and then confirmed that fact by always arguing the patents together. (Lilly Cross-Appellant Br. at 24).

Consistent with Lilly's representation, the Federal Circuit's holding applies equally to both the anxiety and hypertension patents. The court found the '549 patent invalid over the anxiety patent because "[s]erotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal, such as a human, for *any* purpose, including the treatment of anxiety." (Lilly App. at 26a (emphasis added)). "[A]ny purpose" also includes the treatment of hypertension. Thus, under the Federal Circuit's reasoning and express holding, the '549 patent is invalid for double patenting over *both* the anxiety *and* hypertension patents. Consequently, permitting Lilly now to disclaim the term of the '549 patent extending beyond the anxiety patent would be meaningless. The patent would remain invalid over the already-expired hypertension patent.

D. The Federal Circuit Correctly Recognized That Lilly Could Not Resurrect The '549 Patent With A Post-Judgment Terminal Disclaimer.

In any event, the Federal Circuit was right on the merits. Lilly asserts the court's decision was "wholly irrational and unfair" because, according to Lilly, the controlling statute gives it a right to resurrect its patent with a post-judgment terminal disclaimer. But the statute addresses no such issue. *See* 35 U.S.C. § 253 (2001). The statute permits patentees to "disclaim" a portion of their patent monopoly, but does not state that doing so will avoid a judicial finding that a patent is invalid for double patenting. *Id.* And none of the cases that Lilly cites addresses terminal disclaimers filed after a final judgment holding the patent invalid.

Far from holding that a post-*judgment* disclaimer will cure a double-patenting violation, the law does not even hold that a post-*issuance* disclaimer will do so. According to the leading patent treatise, "[n]o decision considers squarely whether a terminal disclaimer entered after the issuance of the second patent will cure a double patenting objection." Chisum, *supra*, § 9.04 [4][b]. Under analogous circumstances, however, the Federal Circuit rejected efforts to adjust the term of a monopoly after the patent issued in *Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1308 (Fed. Cir. 1997). In that case, Abbott initially claimed priority based on the filing date of an early application. *Id.* But when the circumstances later changed to make it advantageous to do so, Abbott attempted to obtain patent protection for 20 years from the date of a later-filed application. *Id.* The Federal Circuit rejected the effort, explaining that Abbott's initial decision was made "to receive the potential benefits" of the earlier date and, thus, "cannot be disregarded simply because it subsequently found that the later filing date would be more advantageous." *Id.*

Here, Lilly decided against filing a terminal disclaimer to obtain an extended monopoly. That choice cannot now "be disregarded simply because" Lilly's attempt to obtain an extended monopoly failed, particularly considering that the '549 patent's value depended partly on its *scheduled* expiration date. Lilly's decision to retain the scheduled expiration of the '549 patent may have "forced [its competitors] into decisions they would not have made had the terminal portion of . . . the patent[] been disclaimed promptly," including decisions relating to product selection and the allocation of research resources. Chisum, *supra*, § 9.04 [4][b] (internal quotation marks omitted).

And even if a post-*issuance* disclaimer could cure a double-patenting violation, a post-*judgment* disclaimer certainly cannot. Any such notion violates the "deeply rooted . . . 'presumption of regularity' that attaches to final judgments, even when the question is waiver of constitutional rights." *Daniels v. United*

States, 532 U.S. 374, 121 S. Ct. 1578, 1583 (2001) (citation and internal quotation marks omitted). Here, in a case with no constitutional implications, Barr asked the Federal Circuit to declare the '549 patent invalid. It is too late now, *after* the Federal Circuit declared the patent invalid, for Lilly to make a new argument that allegedly would "preserve the validity of the ['549] patent." (Lilly Pet. at 28); *accord United States v. Olano*, 507 U.S. 725, 731 (1993) ("No procedural principle is more familiar to this Court than that a constitutional right . . . may be forfeited in criminal as well as civil cases by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it.") (citation and internal quotation marks omitted).

CONCLUSION

In the end, Lilly's arguments in favor of certiorari are wholly insubstantial. As Lilly correctly conceded below, the circumstances of this case are unique and unlikely to ever occur again. Lilly thus is asking this Court to grant certiorari to create case-specific rules that will benefit nobody but Lilly. In fact, for both of its questions presented, Lilly fails to cite even one other case addressing the specified issue. Particularly considering that a 1995 change in the law now eliminates most double-patenting issues, Lilly's proposed rules likely would never apply in any other case in the future. In any event, the Federal Circuit correctly resolved the disputed issues as confirmed by Lilly's refusal to squarely face the long-settled law compelling the court's decision. Thus, the Court should deny Lilly's petition.

Respectfully submitted,

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No. 01-660 (3)

Supreme Court, U.S.
FILED
DEC 11 2001
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In The

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC., and APOTEX, INC., and BERNARD C. SHERMAN, and GENEVA PHARMACEUTICALS, INC., and INTERPHARM, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF INTELLECTUAL PROPERTY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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25 pp

QUESTIONS PRESENTED

1. Did the Court of Appeals err in invalidating Petitioner's basic patent on the antidepressant drug Prozac on the ground that the 1974 discovery claimed by the patent was "obvious" when compared to a second patented discovery that was not even made until 1983, years after the 1974 discovery was first publicly disclosed as "prior art"?

2. Did the Court of Appeals err in ruling that Petitioner was not entitled, despite the plain language of 35 U.S.C. § 253 and uniform precedents applying it, to preserve the validity of its basic Prozac patent by "disclaiming" the final seven months of its patent term held by the court to be an "unjustified timewise extension" of patent exclusivity?

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BRIEF OF INTELLECTUAL PROPERTY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Amici Curiae Robert Brauneis, Mark D. Janis, Jay P. Kesan, Mark Lemley and John R. Thomas (collectively "Intellectual Property Law Professors") respectfully submit this brief in support of petitioner, Eli Lilly and Company ("Lilly"), encouraging the grant of a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.[1]

INTEREST OF *AMICI CURIAE*

Amici are law professors who teach and write about intellectual property law at law schools within the United States. *Amici* are concerned about the continued role of the patent law in stimulating innovation, avoiding the duplicative efforts associated with rivalrous research and development efforts, and forming markets in technological products and processes.

At first glance, the Federal Circuit's decision in this case may appear to involve a narrow technical issue that does not merit this Court's attention. *Amici* are convinced, however, that the decision below undercuts several fundamental principles underlying the patent

[1] Pursuant to this Court's Rule 37.2(a), letters of consent from all parties to the filing of this brief have been filed with the clerk. Pursuant to this Court's Rule 37.6, *amici* represent that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici* made a monetary contribution to the preparation or submission of this brief.

system. The decision causes serious damage to the basic principle that inventors should be able to patent an improvement to their own patented inventions on as favorable a basis as others, and thus deters inventors from continuing to innovate in the field in which they are best equipped to do so. The decision also damages the longstanding principle that newly discovered medical applications of a known compound may be independently patentable, and thus particularly threatens the heavily patent-dependent pharmaceutical and biotechnology industries. Finally, the decision erodes the statutory presumption of validity for issued patents, by requiring that holders of multiple related patents prove that they solicited their patents with all possible speed.

Amici submit this brief to apprise this Court of the importance of the questions presented in this case to fundamental principles underlying the principal mechanism for encouraging technological innovation in the United States. *Amici* urge this Court to grant the petition for certiorari in this case to clarify and reinforce these basic principles of patent law.

SUMMARY OF REASONS FOR GRANTING THE PETITION

The Federal Circuit's decision in this case unwisely elevates the doctrine of "double patenting" from a limited judicial cure of a specific problem to a sweeping basis for striking down patents on improvement inventions. In conflict with patent laws and policies of long application, the decision discourages innovators from refining, advancing and otherwise improving upon their

inventions. The decision will also weigh heavily against patents on pharmaceuticals, biotechnologies and other inventions with biological properties, for it announces a far-reaching doctrine that will block the issuance of patents claiming novel and nonobvious medical uses for known compounds. In conflict with the provisions of the Patent Act and sound patent administration policies, the Court of Appeals has also saddled patentees with the burden of demonstrating that they expeditiously procured their patents.

The Federal Circuit's decision thus implicates fundamental issues in United States patent law, and undermines several basic patent law principles. Because the Federal Circuit has exclusive appellate jurisdiction over patent cases,[2] its decision will weaken innovation policy nationwide unless this Court exercises its power of review. For these reasons, the Court should grant *certiorari* in this case.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Unwarranted Extension of the "Double Patenting" Doctrine Undermines the Fundamental Patent Law Policy of Encouraging Cumulative Innovation.

Technological advance often occurs through incremental developments. Many fields experience cumulative technological advances, in that the sense that today's advances build upon and interface with other features of

[2] 28 U.S.C. § 1295(a) (2000).

existing technology.[3] This pattern of follow-on invention occurs in many significant U.S. industries, ranging from automobiles to semiconductors and computers.[4] In fields such as pharmaceuticals, this pattern of follow-on invention is observed when inventors discover new medical indications for compounds already within the state of the art.

The Patent Act expressly provides that improvement inventions can be independently patented, provided that these inventions are novel and nonobvious.[5] The separate patentability of improvement inventions has traditionally provided important incentives for individuals and enterprises to continue to advance and refine existing technologies.[6] As explained by the late Judge Giles S. Rich:

> The patent system is an incentive system calculated to do two things, principally. First, it stimulates work, research, development, invention, and discovery by holding out the prospect of profit. Second, in exchange for and as a condition of the patent protection, it secures a full disclosure of the invention. Promotion of the useful arts takes place through the combination of these two factors, the doing of the work and the disclosure of the results thereof. In the very nature of things, progress is made as the result

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[3] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

[4] *See* RICHARD R. NELSON & STANLEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE (1982); DEVENDRA SAHAL, PATTERNS OF TECHNOLOGICAL INNOVATION (1981).

[5] 35 U.S.C. § 101 (2000).

[6] *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEXAS L. REV. 989 (1997).

> of both the big and the little contributions, mostly the latter. We get a telephone or a triode – in modern jargon a 'major scientific breakthrough' – only at rare intervals. The seemingly little advances are the bread and butter of progress and sometimes turn out to be of much greater importance than at first thought. The biggest contribution the patent system makes to progress is to induce a steady flow of contributions and to secure their continuous disclosure.[7]

A sound patent system should offer incentives to improve upon basic innovations not only to the patentee's competitors, but to the original inventor as well. Having researched and developed a basic technology, the original innovator often stands in the best position to further perfect the invention. The separate patentability of improvement inventions stimulates inventors to procure patent protection of basic inventions as well. Otherwise, such inventors would justly be concerned that a patent on a fundamental invention might limit their prospects for obtaining patents upon new and nonobvious improvements.

The Federal Circuit's decision in the instant case undermines these established principles. That decision the Federal Circuit struck down U.S. Patent No. 4,626,549 (the "Molloy patent"), Lilly's basic patent concerning fluoxetine hydrochloride. The basis for invalidity was an improvement patent, U.S. Patent No. 4,590,213 (the "Stark patent"), that Lilly had applied for nine years after it filed the Molloy patent application. The Federal Circuit concluded that Lilly had engaged in impermissible double

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[7] *In re Nelson*, 280 F.2d 172, 182 (C.C.P.A. 1960).

patenting and compelled Lilly to forfeit the ostensibly duplicative Molloy patent. The court's unprecedented application of the double patenting doctrine reached an unjust result under the facts of this case. Moreover, the court's extension of the double patenting doctrine holds deleterious consequences for the patent system's goal of sustaining incremental technological advance.

The double patenting doctrine has traditionally prevented an inventor from obtaining multiple patents on inventions that are identical or are obvious variants of one another.[8] The obviousness-type double patenting doctrine is a judicial creation that lacks an expression in the Patent Act. The need for a double patenting doctrine arises because, with the exception of the statutory bars of paragraphs (b) and (d) of 35 U.S.C. § 102, the statutory definition of the prior art generally does not include the inventor's own earlier work.[9] As a result, an inventor's earlier patent applications are ordinarily not considered when an assessment is made whether or not the invention meets the patentability requirements of novelty and non-obviousness.[10]

Absent a double patenting doctrine, an inventor might abuse the patent acquisition process by filing multiple patent applications claiming the same or closely related inventions. Because these applications do not count as prior art against each other, the inventor could potentially obtain numerous patents over a period of

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[8] *See Miller v. Eagle Manufacturing Co.*, 151 U.S. 186 (1894).

[9] *See* 35 U.S.C. § 102 (2000).

[10] *See* 35 U.S.C. §§ 102, 103 (2000).

many years. This technique would allow an inventor effectively to extend the statutory patent term by procuring a series of overlapping patents. It would also expose competitors to suits on several patents rather than one.

Although the double patenting doctrine serves an important role in the patent law, it has not traditionally been applied to the circumstances at issue in this case. Double patenting has previously served as a discrete policing mechanism against the exploitation of a specific statutory loophole. The double patenting doctrine is unnecessary where one patent serves as prior art against another. In such cases, the statutory requirements of novelty and nonobviousness serve to assess whether the later invention presents a patentable advance over the earlier one.[11] As a result, courts and the PTO have applied double patenting principles only when one patent does not serve as prior art against the other.

In this case, Lilly filed the application that led to the Molloy patent on January 10, 1974. The application that led to the Stark patent was filed over nine years later, on April 8, 1983. The disclosure of the Molloy patent serves as prior art against the Stark patent.[12] In fact, the PTO expressly considered the Molloy patent when deciding that the Stark patent should issue. By allowing Stark's

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[11] *See In re Boylan*, 392 F.2d 1017, 1018 n.1 (C.C.P.A. 1968) ("in analyzing cases of these types, it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act (35 U.S.C., as amended).").

[12] *See* 35 U.S.C. § 102 (2000).

application to mature into an issued patent, the PTO already concluded that the invention claimed in the Stark patent presented a novel, nonobvious and patentable advance over the prior art. The PTO's decision is contestable, by accused infringers in a court,[13] or by any member of the public through reexamination proceedings at the PTO.[14] No sound explanation exists for further consideration of the relationship between the Stark and Molloy patents through a judicially crafted doctrine.

This novel application of the double patenting doctrine holds unusual and unjust consequences that were not previously known to the patent system. Prior to the Federal Circuit's decision in this case, the validity of two patents that each claimed new and nonobvious inventions over the prior art did not depend upon their ownership.[15] The Federal Circuit's ruling achieves the bizarre result of tying the validity of an improvement patent to the ownership of the basic patent. If a patent on an improvement is owned by the same entity as the patent on the basic technology, then the double patenting doctrine may defeat one of them even though both patents fully describe and clearly claimed patentable inventions. Yet if the identical patents were owned by different individuals, then their validity would be upheld.

The effect of the Federal Circuit holding is to discriminate among inventors in a manner that is unjust and

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[13] 35 U.S.C. § 282 (2000).

[14] 35 U.S.C. § 302 (2000).

[15] *See Thomson-Houston Electric Co. v. Ohio Brass Co.*, 80 F. 712, 727 (6th Cir. 1897).

economically harmful. Basic inventions may not yet be optimized for the marketplace. Further refinements may be needed, and the party best positioned to achieve these refinements may well be the original inventor. Regrettably, the new double patenting doctrine allows all but the pioneering inventor to obtain proprietary positions in both the original invention and subsequent advancements. Such a rule may discourage inventors from seeking out new uses for known compositions or otherwise optimizing their inventions. It tends to encourage pioneering inventors to employ counterproductive strategies of enterprise organization, so that pioneering and improvement technologies are developed by entities that are formally distinct. And it may also chill the research and development expenditures that lead to pioneering developments in the first place.

Double patenting is a complex doctrine that can be elusive to apply. In this case, the Court of Appeals failed to realize that it should not have employed the double patenting doctrine at all. In so doing, the Federal Circuit departed from precedent and created bad law. By granting *certiorari*, this Court can correct the Federal Circuit's error and prevent its broad-reaching negative consequences.

II. The Federal Circuit's Decision Weighs Heavily Against Inventions with Biological Activity Properties, and Thus Broadly Impacts the Patent-Dependent Pharmaceutical and Biotechnology Industries.

In this case, the Court of Appeals concluded that a patent upon a new and nonobvious anxiety-treating use

of fluoxetine invalidated a patent on the earlier discovery of the serotonin blocking properties of fluoxetine. According to the Federal Circuit, because "the inherent biological function" and "natural result" of administration of fluoxetine hydrochloride is the inhibition of serotonin uptake, Molloy's earlier discovery was intrinsic to Stark's later one.[16] The court therefore invalidated the Molloy patent based upon the Stark patent.

This chain of reasoning was not only inappropriate in this case, but it holds wide-ranging consequences for the pharmaceutical and biotechnology industries. U.S. patent law has for many years recognized that patents may issue for new uses of known compositions of matter.[17] Long-standing precedent also recognizes that accidental, unappreciated prior use of an invention does not bar its subsequent patenting. Many decisions have reasoned that unappreciated events are, by definition, unknown to the public and thus not anticipatory.[18]

Tilghman v. Proctor was one such case.[19] There the patentee claimed "the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure."[20] The accused infringers pointed to several alleged anticipations, ranging from a

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[16] *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 969, 970 (Fed. Cir. 2000).

[17] *See* 35 U.S.C. § 101 (2000).

[18] *See* Bradord J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 539 (1995).

[19] 102 U.S. 707 (1880).

[20] 102 U.S. at 709.

water barometer, to a steam engine, to a method of purifying fats and oils preparatory to soap making. Although the patented method well have been previously performed in connection with these public domain technologies, such performances had not been understood. The Court concluded that these performances would not invalidate the later patent:

> If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery.[21]

Tilghman v. Proctor and subsequent cases have articulated the general rule that an incidental or unknown duplication of an invention cannot constitute an anticipation.[22] The abrupt departure of the Court of Appeals from

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[21] 102 U.S. at 711-12.

[22] One decision of the Court of Customs and Patent Appeals, *Application of Marshall*, 578 F.2d 301 (C.C.P.A. 1978), appears particularly on point. There the applicant claimed a weight control process involving the use of the anesthetic oxethazaine. The PTO cited a prior art reference, the Physician's Desk Reference or PDR, that taught the use of oxethazaine in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. In overturning the PTO's decision rejecting Marshall's application, the court concluded: "Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation." 578 F.2d at 304.

both the terms of the Patent Act and this binding precedent is apparent from the court's methodology used to judge the novelty of the uses to which fluoxetine hydrochloride may be put. In articulating the biological properties of fluoxetine hydrochloride, the Federal Circuit cited no reference from the patent or scientific literature available prior to the filing of Molloy's patent application. Instead, the court exclusively cited documents published after the filing date of the Molloy application. The Patent Act simply does not allow the patentability of inventions to be judged by subsequent technical progress.[23] As observed by Judge Newman in her opinion dissenting from the Federal Circuit's refusal to consider the case *en banc*: "Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work."[24]

The scope of the error in this case exceeds that of the faulty application of hindsight to a particular set of facts. Judge Newman perceptively observed that "every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered."[25] Justice Frankfurter realized as much over fifty years ago, when he stated:

> Everything that happens may be deemed the "work of nature," and any patentable composite exemplifies in its properties "the laws of

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[23] *See, e.g.*, 35 U.S.C. § 103(a) (2000) (mandating that nonobviousness be judged "at the time the invention was made").

[24] 251 F.3d at 974.

[25] 251 F.3d at 955.

> nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.[26]

The reasoning relied on by the court below will weigh heavily against inventions that exhibit biological properties. Many such inventions identify medical indications that were not understood to be associated with the chemical structure of a known compound. As a result, the *Eli Lilly* decision may act to the detriment of two industries, pharmaceuticals and biotechnology, that have the distinction of being both particularly dependent upon the patent system, and fields in which U.S. enterprises enjoy a competitive advantage.

Academic studies have repeatedly shown that enterprises within the pharmaceutical industry view patents as essential to developing and marketing innovations. The widely cited survey conducted by Yale University President Richard Levin and his research associates queried 650 U.S. R&D executives in order to evaluate the effectiveness of patents versus other methods of appropriating private returns. Of all U.S. industries considered by the study, pharmaceutical enterprises most heavily relied upon the presence of a patent system to appropriate returns on their investments.[27]

In 1985, a survey led by former University of Pennsylvania Professor Edwin Mansfield asked chief R&D

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[26] *Funk Brothers Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127 (1948) (Frankfurther, J., concurring).

[27] RICHARD LEVIN, ET AL., APPROPRIATING THE RETURNS FROM INDUSTRIAL RESEARCH AND DEVELOPMENT, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, No. 3, 783 (1987).

executives of 100 U.S. firms what proportion of the inventions they developed between 1981 and 1983 would not have been developed without patent protection. Pharmaceuticals again displayed strong dependence on patent protection. Survey respondents claimed that 60 percent of their drugs would not have been developed without patents. Further, the respondents stated that 65 percent of the drugs would not have been commercially introduced absent patent protection.[28]

The biotechnology industry also appears to rely upon a robust patent law in order to secure capitalization. Reaction to the recent joint statement of U.S. President Bill Clinton and U.K. Prime Minister Tony Blair suggests that investors consider the patent system essential to the viability of private enterprise. In their March 14, 2000, announcement, President Clinton and Prime Minister Blair urged that "raw fundamental data on the human genome . . . should be made freely available to scientists everywhere."[29] A number of biotechnology companies lost a substantial percentage of their market capitalization as investors sold shares in record numbers. The chief concern of many sellers was that biotechnology patent rights would be weakened or subject to uncertainty.[30] The PTO responded by issuing a press release on March 16, 2000, explaining that U.S. patent policy was unaffected by

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[28] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MANAGEMENT SCIENCE 173 (Feb. 1986).

[29] Peter G. Gosselin & Paul Jacobs, "Clinton, Blair to Back Access to Genetic Code," LOS ANGELES TIMES C1 (Mar. 14, 2000).

[30] Greg Heberlein, "Market movers: Biotech bubble pops as Nasdaq falls 200," THE SEATTLE TIMES C1 (Mar. 15, 2000).

the joint statement. As the impact of the Clinton-Blair announcement was better understood, the stock prices of many biotechnology enterprises rebounded.[31]

The *Eli Lilly* decision introduces legal uncertainties that will be keenly felt by those industries that most heavily rely upon the patent system. The broad language of the *Eli Lilly* opinion apparently may be read outside the double patenting context, further impacting the core patentability requirement of novelty.[32] Certainly the Federal Circuit's new standard of inherent anticipation departs dramatically from longstanding patentability requirements on which industry and the patent bar have long relied, and presents a distinct ground for granting *certiorari* in this case.

III. The Federal Circuit's Decision Undermines the Basic Statutory Presumption of Validity of Issued Patents by Imposing Upon Innovators the Burden of Proving Their Patents Were Expeditiously Procured.

The Federal Circuit also announced a troublesome addition to the so-called "two-way" double patenting standard. Under the two-way double patenting standard, a later-issued patent is invalid only if the claims of each patent would have been obvious in view of the claims of

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[31] Bob Woods, "Biotech Stocks Rebound After Analysts Address Clinton Speech," NEWSBYTES NEWS NETWORK (Mar. 15, 2000).

[32] 35 U.S.C. § 102 (2000).

the other patent.[33] Because a species may be patentable over a genus,[34] use of two-way double patenting would appear to render the Stark patent (claiming a method of treating anxiety) patentable over the Molloy patent (claiming a serotonin blocking method).

The Court of Appeals never reached this analysis. Federal Circuit precedent establishes that a patentee obtains the benefit of the two-way double patenting doctrine only if the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first.[35] In this case, the court below concluded that delays in procurement of the Molloy patent were not solely the responsibility of the PTO.[36] The Federal Circuit's evidentiary basis for reaching this conclusion was quite limited, however. The court relied upon no more than the fact that Eli Lilly had filed several continuing applications while prosecuting the Molloy patent, as well as an expert's statement that claim 7 of the Molloy patent could have been procured earlier than it was. Among other issues, the court never considered the prosecution rate of the Stark patent, the difficulty of the issues surrounding the Molloy patent, as well as the pendency of other applications presented to the PTO during this period.

The Federal Circuit should have relied upon more than its intuition that the Molloy patent could have been

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[33] *In re Berg*, 140 F.3d 1428, 1437 (Fed. Cir. 1998).

[34] 251 F.3d at 975 (Newman, J., dissenting from denial of rehearing *en banc*).

[35] *In re Berg*, 140 F.3d at 1437.

[36] 251 F.3d at 969, n.7.

obtained more quickly. The accused infringers did not assert the laches defense in the trial court. Nor did the lower courts find that Eli Lilly had engaged in fraud or inequitable conduct before the PTO. Indeed, because the complete "prosecution history," or record of patent acquisition proceedings in the PTO, was not made of record in this litigation, the lower courts possessed no rigorous basis for evaluating whether the Molloy patent was timely procured or not.

The decision below also holds broader consequences. The Federal Circuit has now saddled patentees with both the burdens of production and persuasion of demonstrating that they solicited their patents with all possible speed. This ruling conflicts with the statutory provision that issued patents bear a presumption of validity.[37] It will also have deleterious consequences upon the administrative process of patent procurement. The complex legal and technological issues so commonplace in the patent law are not always amenable to the hasty resolution compelled by the Federal Circuit's decision.

Commentary in the popular press suggests that some innovators have abused the patent acquisition process by delaying the issuance of their patents.[38] However, the patent community is responding to such abuses through principled reform mechanisms. Statutory amendments

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[37] 35 U.S.C. § 282 (2000).

[38] *See, e.g.*, Charles Ornstein, *Law keeps generics in limbo: Drug makers deny abusing patent rules*, DALLAS MORNING NEWS 1A (June 24, 2001).

now found patent term based upon the application's filing date, rather than the issue date of the resulting patent.[39] As well, a nascent doctrine of prosecution laches is at work in the lower courts.[40] There was no need for the Court of Appeals effectively to impose an irrebutable presumption that a prosecution involved inappropriate delays simply because it was lengthy. This Federal Circuit holding too was in error, and it as well provides a distinct reason for this Court to grant *certiorari* in this case.

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[39] *See* 35 U.S.C. § 154 (2000).

[40] *See, e.g.*, David L. Marcus, *Is the Submarine Patent Torpedoed?:* Ford Motor Co. v. Lemelson *and the Revival of Continuation Application Laches*, 70 TEMPLE L. REV. 521 (1997).

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request that this Court grant the Petition for Writ of Certiorari.

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Dated: December 11, 2001

(4)

No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC., APOTEX, INC., BERNARD C. SHERMAN, GENEVA PHARMACEUTICALS, INC., AND INTERPHARM, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF *AMICI CURIAE* IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Pursuant to Rule 37.2(b) of the Rules of this Court, the Biotechnology Industry Organization ("BIO") and Pharmaceutical Research and Manufacturers of America ("PhRMA") move for leave to file the accompanying brief as *amici curiae* in support of the petition for a writ of *certiorari*. Petitioner Eli Lilly & Co. ("Lilly") has consented to the filing of the brief *amici curiae*; Respondents Barr Laboratories, Inc. *et al.* have withheld consent.

BIO is the principal trade association representing the biotechnology industry in the United States and abroad. Its more than 1,000 members, including nonprofit institutions as well as commercial entities, engage in research, development and commercialization of new technology in the fields of pharmaceuticals, healthcare, food, and agriculture. The biotechnology industry—as well as the revolutionary advances it has provided in the last twenty-five years—would not exist in the absence of a robust patent system. In many instances, the capital needed to establish and grow biotechnology companies has been secured principally by the promise of enforceable patent rights, particularly for those enterprises founded to bring the benefits of federally-funded research to the public through commercial development. BIO is concerned that the decision of the Federal Circuit in this case will severely compromise its members' ability to secure patents that fully and fairly reflect the value of their inventions.

PhRMA is a trade association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. These companies produce the majority of new pharmaceuticals that are developed and

marketed throughout the world. PhRMA's member companies will invest more than $30 billion this year in discovering and developing new medicines, leading the way in the search for cures. PhRMA estimates that each new drug requires about twelve to fifteen years from pre-clinical and clinical testing through FDA approval. This lengthy development period already cuts significantly into the term of patent protection that is supposed to provide manufacturers their best opportunity to recover the enormous development costs of new drug development. The new rule fashioned by the Federal Circuit in this case threatens to curtail that recovery even further by prematurely terminating patent rights for important inventions.

Neither BIO nor PhRMA has a stake in the final outcome of this patent litigation. However, their members, individually and collectively, have an enormous interest in the proper development of the law governing nonstatutory double patenting. Because of the manner in which research, development, and innovation is conducted in the biotechnology and pharmaceutical sectors, BIO and PhRMA anticipate that the fact pattern giving rise to the double patenting issues in this litigation will be encountered frequently. The double patenting rule articulated in the decision below will, in their view, have a disproportionate impact on the industries they represent.

Lilly's petition for a writ of *certiorari* frames the legal issues implicated by the Federal Circuit decision in terms of the particular facts of its case. However, the decision will have important consequences for the business plans and intellectual property strategies of a wide range of research-based companies, including many members of BIO and PhRMA, as double patenting issues arise before the U.S. Patent and Trademark Office. These organizations therefore wish to provide this Court, as *amici curiae*, their perspective

on the wider implications of the Court's review of the decision below.

The decision of the Federal Circuit includes important doctrinal pronouncements that, if not addressed and corrected in this Court's exercise of its supervisory powers, will have serious negative consequences for the procurement of patents for important therapeutic and other inventions. BIO and PhRMA believe that should the decision stand, it will diminish the patent system's incentives for innovation—the foundation of the biotechnology and pharmaceutical industries.

In keeping with Supreme Court Rule 37.1, the proposed brief *amici curiae* draws the Court's attention to important legal issues of double patenting that are encompassed by, but not discussed at length in, the petition for a writ of *certiorari*. BIO and PhRMA believe that the more thorough development of these issues will be of material assistance to the Court in evaluating the petition.

For the reasons set forth above, BIO and PhRMA request that this Court grant the present motion for leave to file the enclosed brief as *amici curiae*.

Respectfully submitted,

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BRIEF *AMICI CURIAE*

Under cover of the accompanying motion pursuant to Rule 37.2(b) of the Rules of this Court, the Biotechnology Industry Organization ("BIO") and Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully submit this brief *amici curiae* in support of the grant of a writ of *certiorari*.[1]

INTERESTS OF THE *AMICI CURIAE*

BIO is a trade association consisting of more than 1,000 companies, academic institutions, and biotechnology centers. BIO members file thousands of patent applications each year for inventions ranging from fundamental technological breakthroughs to important commercial refinements of existing technology.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, and serves as the industry's principal policy advocate. Relying heavily on patent protection to develop and commercialize new therapies, PhRMA members account for more than 75% of brand name drug sales in the United States.

Members of BIO and PhRMA depend on the incentives of the patent system. *Amici* are thus concerned that the law of double patenting be applied consistently and fairly, and in accord with the policy objectives of the patent system.

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[1] Pursuant to Rule 37.6, *amici curiae* state that no person or entity other than BIO, PhRMA, or their counsel has made any monetary contribution to the preparation or submission of this brief. Petitioner Eli Lilly and Co., though a member of both BIO and PhRMA, did not participate in discussions related to the filing of this brief and, apart from paying regular membership dues, did not contribute to the cost of its preparation. No counsel for Petitioner or Respondents authored this brief in whole or in part.

SUMMARY OF THE ARGUMENT

The decision of the Federal Circuit in this case will lead to severe and undesirable changes to practice before the Patent and Trademark Office ("PTO"). It forces consideration of "double patenting" questions in situations not warranted by precedent, and it invents a new rule that will drastically restrict access to the "two-way" test for nonstatutory double patenting, discussed *infra*. The analysis applied by the court below threatens to diminish the effectiveness of the patent incentives that are critical for the biotechnology and pharmaceutical industries.

This Court has recognized that "an inventor may make a new improvement on his own invention of a patentable character." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 199 (1894). Independent patents for merely "obvious" variations of a first patented invention, however, are prohibited on the theory that granting the second patent would improperly prolong the period of exclusivity beyond the term fixed by statute. Rules against such "double patenting," developed through patent jurisprudence, prevent the *improper* extension of patent rights.

Difficult double patenting questions arise when the grant of a patent on a basic invention is delayed in the PTO until after the grant of a separate patent on a later-filed application for an improvement on the basic invention. In this situation, the PTO must determine whether the separate inventions claimed in the patents deserve independent or linked patent terms. If the PTO concludes the applicant is not entitled to a distinct term for each invention, it may require the applicant to truncate the term of the later-issuing patent.

In these reverse-order situations—where the PTO has already concluded that the later issuing patent claims would not be separately patentable over the earlier patent, absent extenuating circumstances—past precedent of the Federal

Circuit instructed the PTO to consider the patent applicant's behavior as a whole in determining whether the term of the later-issuing patent should be cut short. If the patent applicant is not principally responsible for controlling the rate of prosecution of the two patents (*i.e.*, for creating the "reverse-order" situation), the PTO will instead use what is termed the "two-way" test for patentability, which ordinarily will result in a decision to grant full, unlinked terms for both inventions.

In the decision below, the Federal Circuit has transformed this evaluation into a *de facto* ban on use of the two-way test. It would deny access to the two-way test upon any finding of a single instance of "delay" attributable to the applicant. The decision below conflicts with—but does not purport to overrule—Federal Circuit precedent that looks to the record *as a whole* to assess the applicant's conduct. Its rule will fall most heavily on patent applicants in new technologies, imposing requirements that will be difficult for even the most diligent to meet. As a result, many innovators will be forced to forego the full measure of protection for each of their separately patentable inventions.

Patent policy, as well as the need for clarity and consistency in this commercially vital area of the law, are concerns of national importance. This Court's exercise of its supervisory power is therefore warranted.

ARGUMENT

In the decision below, the Court of Appeals for the Federal Circuit articulated a new rule for evaluating nonstatutory double patenting. This new rule represents a significant departure from established law, implicating important questions of patent policy, and thus calls for the exercise of this Court's supervisory power. The reasoning adopted by the Federal Circuit will directly and inevitably affect the practices of innovators in patenting new and useful improvements on patented technology. Federal

Circuit law is binding for all patent litigation in the district courts and for all proceedings before the PTO. The effect of the decision below is therefore far-reaching and, *amici curiae* believe, raises questions of national importance.

The questions presented to the Court involve nonstatutory double patenting—whether a patentee has improperly extended the grant of exclusivity by separately patenting a second, related invention. The rules in this area of the law reflect basic policy decisions—made by the courts—about when an inventor should or should not be entitled to separate and distinct patents for each of two inventions. These rules are of enormous importance to innovation-driven enterprises with extensive research programs, such as the members of BIO and PhRMA. However, the new rule announced below virtually precludes the possibility of the PTO issuing independent patents to a single entity for both an original, "basic" invention and a later, *fully patentable* "improvement" invention under certain circumstances. Because it threatens to deter the early disclosure of original inventions, this decision bears close scrutiny.

The Court of Appeals for the Federal Circuit twice held a claim of U.S. Patent No. 4,626,549 ("the '549 patent), owned by Eli Lilly and Co. ("Lilly"), invalid on grounds of nonstatutory double patenting. *See Eli Lilly and Co. v. Barr Laboratories, Inc. et al.*, 251 F.3d 955 (Fed. Cir. 2001), Pet. App. at 1a, *vacating en banc* 222 F.3d 973 (Fed. Cir. 2000), Pet. App. at 57a. In its second panel decision, based on different grounds than the first, the court held that the claim of Lilly's earlier-filed but later-issuing basic invention patent was invalid in view of a claim that had been granted for a *later-filed but earlier-issued* improvement invention. The basic legal issue—double patenting involving claims that issue in "reverse order"—has been addressed in several Federal Circuit decisions. In this case, however, the court departed from its established precedent to fashion a new,

mechanical rule, under which *any* "delay" in the prosecution of the patent that cannot be attributed solely to the PTO will compel a decision adverse to the patentee. *See Lilly*, Pet. App. at 24a-25a, n.7.

Amici curiae urge this Court to grant the petition with respect to the first question presented, namely, whether the Court of Appeals erred in invalidating claim 7 of the '549 patent on grounds of nonstatutory double patenting.[2] *Amici* note Lilly's arguments that the Federal Circuit's invocation of double patenting analysis was improper from the outset. *Amici*'s focus in this brief, however, is on the fact that in addressing double patenting (whether or not it was proper to do so), the Federal Circuit applied a legal analysis that was inconsistent with its own settled precedent and that represents a significant shift in the law. The *Lilly* decision defines a virtually unattainable standard for developers of basic and improvement inventions to avoid a charge of double patenting when their patents have issued in reverse order. In its petition, Lilly addresses this issue with respect to the law of laches, Pet. at 21-23. *Amici* discuss it *infra* in terms of the "one-way" and "two-way" tests the Federal Circuit and its predecessor court have developed for assessing double patenting under this fact pattern.

The availability of patents for improvement inventions—*i.e.*, later-discovered inventions that improve upon an earlier basic innovation—is a crucial stimulus to innovation in any area of technology. It is especially important in the biotechnology and pharmaceutical industries, where both basic and improvement patents afford critical protection as the fruits of research are developed and

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[2] *Amici* express no views regarding the second question presented in the petition, which asks whether the court below properly held that Lilly could not cure an infirmity based on double patenting by disclaiming the terminal portion of the term of the '549 patent after it had issued.

improved to bring new drugs, therapies, and other products to market.

I. The Law of Double Patenting.

"Double patenting" refers generally to the improper procurement of two patents for the same invention.[3] The doctrine, developed through case law with little direction from Congress, is rooted in the constitutional authority to secure for inventors exclusive rights in their discoveries "for limited Times," U.S. Const., art. I, § 8, and in the provision of the Patent Act that an inventor may obtain "a patent"—that is, a single patent—for an invention, 35 U.S.C. § 101. A summary of its origin and key rules is necessary to appreciate the impact of the decision below.

A. Evolution of the Law of Double Patenting.

Disputes over double patenting date back almost to the enactment of the first patent statute. In a case involving patents issued to one Jesse Reed in 1807 and 1810, for example, Justice Story (sitting as Circuit Justice) held:

> It cannot be, that a patentee can have in use at the same time two valid patents for the same invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century. . . . [T]he inventor can have but a single valid patent for his invention; and . . . the first he obtains, while it remains unrepealed, is an estoppel to any future patent for the same invention founded upon the general patent act.

Odiorne v. Amesbury Nail Factory, 18 F. Cas. 578, 578 (C.C. D. Mass. 1819).

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[3] As discussed below, "same invention" is a term of art in double patenting law. It is used here in its nontechnical sense.

In 1894, this Court observed:

> It is settled . . . that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent; and the cases . . . come to this point, and to this point only: That a letter patent may be granted where the invention is clearly distinct from, and independent of, one previously patented.

Miller, 151 U.S. at 199. In that case, however, "every claim of the 1881 patent could have been properly included and made a part of the claims of the 1879 patent." *Id.* at 201. Accordingly, "[t]he matter sought to be covered by the second patent is inseparably involved in the matter embraced by the former patent; and this, under the authorities, renders the second patent void." *Id.* at 200.

A fact situation similar to that of the present litigation arose at least as early as *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315 (1865). Hayden had filed a first patent application in 1854 for an improvement in a cotton cleaning machine, described separately and in combination with other features. In 1857, Hayden filed what would today be considered a divisional application directed to the improvement alone, and a patent was granted on that application the same year. "For some cause, however, the commissioner had not acted on [the 1854] application down till June, 1857," *id.* at 316, and did not grant a patent until 1860. This Court held that "[t]he last [patent], not the first, is void," *id.* at 319, notwithstanding that "[i]t did not appear that Hayden was guilty of any laches, or was in any default in reference to the delay of the commissioner," *id.* at 316.

In a series of cases beginning in the early 1960s, the Court of Customs and Patent Appeals ("C.C.P.A."), and later the Federal Circuit, refined the analysis for comparing claims in two patents or applications to determine whether

they are patentably distinct. It drew a distinction between double patenting involving claims that are effectively identical in scope and content, on the one hand, and double patenting based on claims of divergent scope, on the other. *See In re Vogel*, 422 F.2d 438, 441-442 (C.C.P.A. 1970). It found a basis for the former, which it termed "same invention" double patenting, in 35 U.S.C. § 101, which it construed to proscribe the grant of more than one patent containing identical claims. *Id.*

For claims of differing scope, the C.C.P.A. determined that the proper analysis was *analogous to*, but distinct from, that employed to assess obviousness under 35 U.S.C. § 103; hence the term "obviousness-type double patenting." *Id.* In particular, the test looks to whether the differences between the *claims* (rather than between the prior art and the thing claimed) would have been obvious to one having ordinary skill in the art, structuring the inquiry in the manner instructed by *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), in the context of § 103. *See generally In re Vogel*, 422 F.2d at 441-442. A claim may also be found unpatentable or invalid on these grounds if, in analogy to 35 U.S.C. § 102, it is "anticipated" by—that is, if it is broader than—a patented claim. *See, e.g., In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993). Because the C.C.P.A. and Federal Circuit have found that this type of double patenting lacks an express statutory basis, it is also referred to as "nonstatutory" double patenting.[4]

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[4] Because "obviousness-type" is somewhat confusing where double patenting is demonstrated without reference to an obviousness analysis, *i.e.*, where one claim "anticipates" another, this brief employs the term "nonstatutory" double patenting.

B. Terminal Disclaimers Equitably Resolve Double Patenting Problems.

Prior to the 1952 Patent Act, ch. 950, 66 Stat. 809 (1952), the unavoidable consequence of double patenting was the invalidity of the later-issued claims. In that Act, however, Congress provided a mechanism in the form of the "terminal disclaimer," 35 U.S.C. § 253, which proved useful to equitably resolve double patenting problems within the PTO. Through this device, a patent owner may disclaim the portion of the term of a second-issuing patent that extends beyond the term of a first-issuing patent, and thus cause the second patent to expire on the same date as the first.[5] Concerns about an "unjustified timewise extension" of exclusivity, condemned under double patenting jurisprudence, thus become moot. *In re van Ornum*, 686 F.2d 937, 943-44 (Fed. Cir. 1982); *see In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring).[6]

A valid terminal disclaimer requires the patent owner to retain ownership of the terminally disclaimed patent and the referenced patent. *See* 37 C.F.R. § 1.321(c)(3). This requirement protects the public from harassment in the form of lawsuits brought by multiple parties holding patents to inventions that are not patentably distinct. A terminal disclaimer renders the two patents legally inseparable, as though all of the claims had in fact been issued in a single

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[5] Even under a patent term measured as 20 years from the earliest claimed filing date, 35 U.S.C. § 154(a)(2), related patents will not necessarily expire on the same date. Such patents need not arise from the same original application, and patent terms may be adjusted independently to compensate the applicant for administrative delays in examination, 35 U.S.C. § 154(b).

[6] The late Judge Rich, who suggested the use of a terminal disclaimer to "cure" double patenting in *Zickendraht*, was—not coincidentally—a principal architect of the 1952 Patent Act.

patent. It is thus the practice of the PTO to require a terminal disclaimer when the claims of a later application are not separately patentable over (*i.e.*, are anticipated by or obvious in view of) the claims of a prior issued patent. These issues are discussed in *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998), to which *amici* commend this Court's attention as a particularly lucid exposition of the law at issue in this case.

C. The Two-Way Test Allows Independent Patents for Basic and Improvement Inventions, Regardless of the Order in Which the Patents Issue.

The law governing double patenting, properly applied, ensures that separate patents having distinct terms will be granted when justified—that is, where the claims of the two patents define patentably distinct inventions, as elaborated in *In re Vogel*, 422 F.2d at 441-442, and its progeny. Thus where an improvement invention, such as a chemical species, is claimed after the grant of a patent on a related basic invention, such as a chemical genus,[7] the claim to the species will merit a distinct and separate patent term if the species is novel and nonobvious over the genus.[8] In the

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[7] A chemical "genus" is a class of compounds sharing structural similarities, while a "species" is a single compound within the class defined by the genus. Many important pharmaceutical inventions involve discoveries of unique, therapeutically useful species within a previously known class of chemical compounds (the genus).

[8] A claim to a species is patentable (not obvious) over a description in the prior art of a genus that includes it unless the prior art provides some specific motivation to select the species. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). The converse, however, is not true: a prior art description of a species anticipates any later claim to a genus that

ordinary case, *i.e.*, where an improvement invention is distinct from an earlier, patented basic invention, no terminal disclaimer will be required.[9]

This analytical framework breaks down, however, when—for whatever reason—the examination of the basic patent is delayed, and the PTO issues the improvement patent first. In the example of a chemical genus and species, a claim to a species in a first-issuing, but later-filed, patent would then "anticipate" a claim to the genus in a later-issuing patent. *See, e.g., In re Goodman*, 11 F.3d at 1053.

To preserve the right of a patent applicant in this situation to secure *both* a patent on a basic invention and an independent patent for a later improvement invention meeting all of the requirements for patentability, the Federal Circuit established a "two-way" test, whereby the PTO or a reviewing court must determine that the claims of *each* patent are unpatentable over the claims of the other before a terminal disclaimer may be required. *In re Braat*, 937 F.2d 589, 592; *In re Berg*, 140 F.3d at 1432. In contrast, a "one-way" test asks simply whether the claims of the later-issuing patent are unpatentable over the claims of the first, without regard to the order in which the patents were filed.

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includes it, rendering the generic claim unpatentable under § 102. *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960).

[9] A rule that automatically imposed a requirement for a terminal disclaimer in such circumstances would unfairly penalize the patent holder, denying a full patent term for a patentable improvement. The first panel decision in these proceedings, Pet. App. at 57a, *vacated en banc* Pet. App. at 37a-38a, did announce such a rule, prompting no fewer than six parties, including the present *amici*, to file briefs *amici curiae* urging the Court of Appeals to rehear the case *en banc*. The second panel decision does not suffer from the same infirmity.

D. The Two-Way Test Is Applied Infrequently But Is Critically Important When Invoked.

The two-way test preserves the right of the inventor of both basic and improvement inventions to enjoy a full term of patent rights for each of his two patentable inventions. It is particularly important in the biotechnology and pharmaceutical industries, where applications claiming a genus and a species often do not issue in the order in which they were filed.

Before *Lilly*, the jurisprudence of the Federal Circuit and C.C.P.A. held that access to the two-way test was to be based on an evaluation of which party—the PTO or the applicant—controlled the relative rates of prosecution of the two applications. Under that standard, the two-way test "is a narrow exception to the general rule of the one-way test." *In re Berg*, 140 F.3d at 1432. Access to the two-way test thus traditionally has been reserved for situations where the prosecution of the later-issuing patent is delayed in the PTO for reasons largely beyond the applicant's control—for example, where an appeal is not promptly decided or where an interference proceeding is conducted.

As Lilly discusses at length in its petition, the PTO *affirmatively determined* the patentability under §§ 102 and 103 of its claim to the later-filed improvement invention over its patent describing the basic invention. As a result, a double patenting analysis arguably should never have come into play in the Federal Circuit's decision. Moreover, had the Federal Circuit properly applied a two-way test, the '549 patent would not have been found invalid on the grounds cited in *Lilly*. The fact that the two patents issued with unlinked terms supports the notion that the PTO did not consider Lilly's prosecution of the later-issuing patent to be dilatory.

Quite apart from any impropriety of introducing the question of double patenting into this case, however, *amici*

wish to call the Court's attention to the Federal Circuit's *ensuing misapplication* of the law governing access to the two-way test. In its decision, the court below announced a new, blunt standard that prejudices the legitimate interests of patent owners who are not dilatory in prosecuting their applications before the PTO. Under the new rule, the court asks whether the PTO was "*solely* responsible" for any delay in prosecution, *Lilly*, Pet. App. at 24a-25a, n.7 (quoting *In re Berg*,[10] 140 F.3d at 1437; emphasis supplied by the *Lilly* court). The new standard essentially dictates that a one-way test will be imposed on "reverse-order" patent applicants in all but the most exceptional situations. The consequences of the new standard—effectively, the denial *a priori* of the full term of patent protection for some patentable inventions—are so powerful as to warrant this Court's review.

II. *Certiorari* Should Be Granted Because *Lilly* Conflicts with Federal Circuit Precedent Without Overruling It, Leading to Confusion in the Law.

One of the questions raised by the *Lilly* decision is how a patent applicant's conduct before the PTO should affect a double patenting analysis when the patents are issued in reverse order. The answer to this question determines whether a patent providing the full statutory term of exclusivity, *i.e.*, free of a terminal disclaimer, will be granted over a patent "for an improvement of a patentable character . . . where the invention is clearly distinct from, and independent of," the basic invention claimed in the later-issuing application, *Miller*, 151 U.S. at 199.

The trend in the Federal Circuit's decisions in the last decade has been toward more restricted, albeit considered, application of the two-way test in reverse-order nonstatutory

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[10] The quoted phrase occurs in a discussion of a legal rationale that the *Berg* court did *not* apply on the facts before it.

double patenting situations. Nevertheless, the wooden rule announced in *Lilly* is incompatible with those decisions, as it unjustifiably constrains the analysis in a manner dangerous to patent policy and technological innovation.

In *In re Braat*, 937 F.2d at 593-594, the Federal Circuit formalized an approach for the treatment of claims in reverse-order situations. Reasoning that "an applicant . . . who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control," the court found that "it is not [the assignee's] fault that the combination claims in the ["improvement"] patent issued first." *Id.* at 593-94. On the facts of that case, it held that a two-way test should be applied.

In re Goodman, in contrast, applied a one-way test to generic claims in a continuing application having the same disclosure as its patented "parent," which claimed a species encompassed by the later-claimed genus. Finding that "PTO actions did not dictate the rate of prosecution" of the later application, the court held the broader claims unpatentable in the absence of a disclaimer. *Id*, 11 F.3d at 1053. Similarly, *In re Emert*, 124 F.3d 1458, (Fed. Cir. 1997), denied the applicant use of the two-way test because it had "orchestrated the rate of prosecution for the two applications." Having delayed a substantive response to the PTO for two years by taking extensions of time and filing continuation applications, the applicant was held "responsible for the delays in prosecution." *Id.*, 124 F.3d at 1461.

In *In re Berg* the applicant sought to test the independent patentability of claims to a genus and an included species by simultaneously filing separate, unrelated, but substantially identical applications. Finding the "control of prosecution rates" standard improper on the facts of that case, the court applied a one-way test "because

Berg could have filed the claims of its separate applications in a single application, and it simply chose to file two applications despite nearly identical disclosures." *Id.*, 140 F.3d at 1433.

Each of these decisions reflects a consideration of the patentee's behavior in light of the prosecution history *as a whole* to ascertain whether the application of the two-way test, and thus the absence of a terminal disclaimer, would result in an "unjustified timewise extension of the right to exclude granted by a patent," *In re Braat*, 937 F.2d at 594. This language resonates in equity. Taking due regard of the public interest, the Federal Circuit—prior to *Lilly*—has followed an essentially equitable approach, taking account of *all* of the relevant facts to determine the availability of the two-way test in its nonstatutory double patenting analysis.

The Federal Circuit's opinion in *Lilly* represents a significant departure from the approach of *Braat*, *Goodman*, *Emert*, and *Berg*. The only indication that the court even considered Lilly's actions before the PTO is found in a single footnote, where the panel concluded that "... the PTO was not solely responsible for the delay." *See Lilly*, Pet. App. at 24a-25a, n.7. The opinion did not otherwise consider the nature of the delay or whether Lilly's actions were objectively reasonable or appropriate.

The rule under *Lilly* is virtually automatic. In the face of *any* evidence of *any* delay arguably caused by the applicant, the two-way test will be denied. *Amici* contend that Federal Circuit precedent requires a more detailed and context-sensitive inquiry than that set forth in *Lilly*. Principles of equity and fairness warrant the award of a complete term of patent protection when the grant of a second patent is delayed for reasons beyond the exclusive control of the applicant. Retention of the *Lilly* standard, which grants full and independent terms only when the PTO is "*solely* responsible" for the delay, will unreasonably prejudice the ability of innovators to enjoy such protection,

and these conflicting precedents will create confusion in the law.

III. *Certiorari* Should Be Granted Because *Lilly* Significantly Affects Important Questions of Patent Policy, Threatening Great Harm to Technological Innovation.

Patent applicants often claim their inventions broadly at an early stage and then more narrowly as the inventions are refined and further developed, particularly as the commercial application of the technology becomes clear. Basic and improvement patents each promote innovation, and patents on each provide critical incentives for bringing a stream of new and improved products to market.

There are serious consequences for public policy in the *Lilly* court's rule. Unchecked, it will lead to an effectively *per se* rule in the PTO, imposing the one-way test on all patents that issue in reverse order and resulting in unjustified requirements for terminal disclaimers. Worse, it will lead to the inappropriate invalidation of claims in distinct patents that *each* fully meet the requirements for patentability. The significant harm to innovators that would flow from the broad application of the new rule strongly militates in favor of review by this Court of the decision below.

A. The *Lilly* Rule Will Discourage Innovation.

The wooden formula announced by the Federal Circuit will ensnare many patent applicants who have prosecuted their patents promptly and in good faith but have taken some action that can be characterized as contributing in some manner to a delay before the PTO. Regardless of the facts before the court in *Lilly*, its legal rule is cast in such absolute terms that it is hard to imagine when *any* reverse-order patentee would be entitled to the two-way analysis.

The new rule will render the two-way test inaccessible in all but the most unusual situations, leading to profound

consequences. Applicants will often have no choice but to file terminal disclaimers to obtain comprehensive protection for all of their inventions. Without disclaimers, their later-expiring patents will be at risk of being invalidated altogether. In the view of *amici*, this result would be unfortunate and undesirable as a matter of public policy.

The last years of the patent term frequently yield the greatest economic return on commercially successful inventions, notably for those in the biotechnology and pharmaceutical industries, and, as such, provide a potent incentive to innovation. The premature termination of patent rights by disclaimer will significantly diminish the value of patents on inventions that fit this profile and will limit the capacity of the patent system to stimulate research and the refinement of inventions.[11]

Even for inventions that are not commercial blockbusters, a rule that too frequently forces the submission of terminal disclaimers will be harmful to the commercialization of inventions. Disclaimers not only curtail patent terms, but also require continuing common ownership of the cited and disclaimed patents. *See In re van Ornum*, 686 F.2d at 944-945; 37 C.F.R. § 1.321(c)(3). Where there is more than one patentably distinct improvement invention—for example, different drugs developed from a class of compounds—terminal disclaimers involving the same basic patent will preclude the independent transfer of rights to the patents. Restrictions on

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[11] Through enactment of the American Inventors Protection Act of 1999 ("AIPA"), Pub. L. 106-113, 113 Stat. 1536, the Congress demonstrated its commitment to principles of balance and fairness in adjusting the term of a patent. *See* AIPA § 4402, *codified at* 35 U.S.C. § 154(b), providing for an extension of term equal to the total of delays attributable to the PTO, less any delays attributable to the applicant, as compensation to the patentee for failure of the PTO to examine an application in a timely manner.

transferability tend to lower the value of patents and ultimately impede the commercialization of new products.

Together, these factors will discourage use of the patent system in favor of trade secret protection, particularly for early-stage inventions. That, in turn, will deprive the public of early access to information on significant technological advances, including through the publication of patent applications as provided by 35 U.S.C. § 122(b). It is critical that the rule to determine the availability of the two-way test be fair and reflect due consideration of all of the affected interests.

B. Rapidly Developing Fields of Technology Are Particularly Vulnerable.

Patent applicants in competitive and rapidly developing areas of technology, such as biotechnology and computer-aided drug design, are especially susceptible to having patents on basic and improvement inventions issue in reverse order. Inventors in these fields must file their applications as they make their discoveries or risk a loss of patent priority. Yet claims to early-stage inventions typically take longer to examine simply because they are broad, requiring more extensive searches and raising more patentability issues than focused claims to defined improvements. Compounding the problem, the law and the PTO's administrative resources often fail to keep pace with the changing nature of inventions in these areas, delaying the examination of pathbreaking basic inventions further. Reverse-order double patenting problems are thus more likely to occur in the very fields where patent protection is most critical to securing a competitive advantage.

Emerging companies in new fields are often in a poor position to contest a rejection by the PTO based on double patenting. Many pharmaceutical and biotechnology innovators have no assets other than their *potential* patent rights. Many smaller companies, faced with double

patenting rejections, will elect to comply with requirements for terminal disclaimers to gain allowance of their patents, rather than invest time and scarce resources in an appeal. This is all the more likely where the controlling legal rule is so mechanical in its operation, and so easily triggered, as to disallow *a priori* almost any rebuttal evidence.

Because there is no statutory provision to withdraw a terminal disclaimer, the consequences of the *Lilly* rule are especially harsh. Once a disclaimer under 35 U.S.C. § 253 has been executed, the disclaimed term is irretrievably forfeited. Applicants have no option to provisionally disclaim part of the patent term pending resolution of their legal arguments before the Federal Circuit.

C. Patent Applicants Should Not Automatically Forfeit Rights for Any and All Prosecution Delays.

The *Lilly* rule holds that a delay that can be attributed *in any manner* to the applicant will act as a bar to use of the two-way test. Yet there are many situations where actions that arguably delay the grant of the patent are entirely legitimate practices endorsed by statute and regulation. For example, an applicant may take an extension of time to submit a response to a complicated rejection, or file a continuing application to further prosecution rather than appeal. Only on review of the *complete* prosecution history will it be clear whether the applicant's actions in their entirety constitute a deliberate pattern of delay.

An automatic result, based on evidence divorced from the context of the entire prosecution history, is not true to the equitable roots of double patenting jurisprudence. Neither is it true to this Court's observation that "[i]t is settled . . . that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent." *Miller*, 151 U.S. at 199.

Amici believe that it is proper to divest a dilatory patent applicant of the protections of the two-way test. *De facto* elimination of the two-way test itself, however, will punish patent owners severely for any action during prosecution that can be characterized as even contributing to a delay. Basic fairness mandates that the legal rule for denying the two-way test invoke more than a cursory review of the prosecution history for which the applicant is to be held accountable.

D. Action By This Court Is Necessary To Restore a Proper Balance in the Law.

The effect of the *Lilly* decision will be felt most acutely by patent applicants. The PTO will undoubtedly provide guidance to its examiners concerning the application of *Lilly*. Even if the guidance urges restraint, however, *amici* fear that many examiners, already overburdened by the PTO's enormous and ever-increasing caseload, will gravitate toward the stark simplicity of a rule that requires a one-way test upon the identification of any minor "delay," whatever the intrinsic merits of the rule. It is simply human nature to resort to an expedient solution when it is available.

The current fractious state of the law prejudices the legitimate interests of patent applicants, litigants, research-based industries, and the public. This Court's guidance is now required to reconcile conflicting Federal Circuit precedents and to preserve the incentives for innovative improvements that the Court has recognized for more than a century.

CONCLUSION

For the foregoing reasons, *amici curiae* BIO and PhRMA respectfully request that this Court grant the petition for a writ of *certiorari*.

Respectfully submitted,

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December 13, 2001

MOTION FILED
DEC 13 2001

(5)

No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY & COMPANY,
Petitioner,

v.

BARR LABORATORIES, INC., APOTEX INC., and BERNARD C. SHERMAN, GENEVA PHARMACEUTICALS, INC., and INTERPHARM, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF CERTIORARI

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MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF CERTIORARI

Pursuant to this Court's Rule 37.2, Intellectual Property Owners Association (IPO) respectfully moves for leave to file the attached brief *amicus curiae* in this case. The consent of the petitioner has been obtained. The consent of the respondent Barr Laboratories, Inc. was requested but refused.

Amicus IPO is a national organization that represents the owners of intellectual property in the United States. IPO's members include businesses and individuals who own or are interested in intellectual property rights. IPO regularly represents the interests of its member before Congress, the U.S. Patent and Trademark Office, and federal courts. The

association adheres to a policy of submitting *amicus* briefs only on significant issues affecting the owners of intellectual property rights.

IPO and its members have a substantial interest in the questions presented by the petition in this case. IPO members receive about 30 percent of patents granted by the U.S. Patent and Trademark Office to U.S. nationals. They may own many patents for basic inventions that were filed before but granted after patents for improvements in the basic invention.

In filing this brief, IPO seeks to bring to the Court's attention arguments and viewpoints in addition to those expressed in the petition for writ of certiorari. For example, IPO's brief points out that the Federal Circuit decision not only will harm owners of basic patents that were available as prior art with respect to improvement patents, as in the Lilly case, but also will harm owners of basic patents that were not available as prior art. IPO's brief expressly supports the doctrine of prosecution laches, citing *Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463 (1924). In summary, IPO's brief provides the Court with the perspective of a national association having members in all major industries and fields of technology, and the perspective of parties concerned about the effects on the patent system beyond the present case.

Respectfully submitted,

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae Intellectual Property Owners Association (IPO), a tax-exempt association, is a national organization founded in 1972 to represent the owners of intellectual property in the United States.[1] IPO's members currently

[1] Pursuant to this Court's Rule 37.6, *amicus* represents that this brief was not authored in whole or in part by counsel for any party. Petitioner, an IPO member, made no monetary contribution to the preparation or submission of this brief beyond normal membership dues payments. No other person or entity made a monetary contribution other than IPO, its members, or its counsel.

include about 100 large and mid-sized companies and 250 small businesses, law firms, inventors, authors, executives and attorneys who own or are interested in patents and other forms of intellectual property in any industry or field of technology. IPO members receive about 30 percent of patents issued by the U. S. Patent and Trademark Office to U. S. nationals. IPO regularly represents the interests of its members before Congress and the U.S. Patent and Trademark Office, and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law.

IPO expressly declines to take any position on whether there is a factual basis for finding Lilly's claims to be invalid or unenforceable. IPO is concerned with the interests of all of its members in all industries and all fields of technology. IPO believes that the Federal Circuit misapprehended the law, and that the precedents established by the Federal Circuit's opinion, if it is not vacated or modified, will adversely affect existing and future patent rights of a large number of IPO members.

In this brief IPO explains misapprehensions of law that could affect the outcome of this and future cases. IPO believes its brief will be helpful to the Court in considering Lilly's petition for writ of certiorari. The filing of this brief was approved by the IPO Board of Directors, the members of which are listed in the Appendix.[2]

INTRODUCTION

The case concerns the validity of certain claims within a family of patents issued to Lilly relating to pharmaceutical compounds and methods of use of pharmaceutical compounds including fluoxetine hydrochloride, the active ingredient in Prozac®. The Federal Circuit concluded that

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[2] Eli Lilly & Co., which is represented on the Board, did not vote on whether to file the brief.

claim 7 of Lilly's '549 Molloy patent is invalid for so-called obviousness-type double patenting in view of claim 1 of Lilly's '213 Stark patent.

The '549 Molloy patent is a basic patent ("the basic patent") that relates to blocking the uptake of serotonin in an animal's brain neurons though the administration of Prozac®. The '213 Stark patent is an improvement patent ("the improvement patent") for the use of Prozac® to treat anxiety.

The basic patent, which was "first in, last out," was first filed for in a parent application on January 10, 1974, and was issued on December 2, 1986. The improvement patent was filed for on April 8, 1983 and issued on May 20, 1986, 7 months before the basic patent. The Federal Circuit determined that claim 7 in the *basic* patent was obvious in view of the earlier-issued *improvement* patent, and therefore, the *basic* patent is invalid for obviousness-type double patenting.

SUMMARY OF ARGUMENT

When a basic patent is filed before but issued after an improvement patent, the order of issuance is disregarded and the later-issuing basic patent is upheld if the improvement patent is not obvious in light of the basic patent. The Federal Circuit has misapprehended this rule of law, which applies in the absence of inexcusable delay. A patent owner should not be penalized for late issuance of a basic patent unless there was prosecution laches. The Federal Circuit decision will discourage inventors from applying for basic and improvement patents. The Federal Circuit also has misapprehended the law governing disclaimers of the terminal portion of a patent.

ARGUMENT

I. THE FEDERAL CIRCUIT MISAPPREHENDED THE LAW OF OBVIOUSNESS-TYPE DOUBLE PATENTING AS IT RELATES TO A BASIC PATENT FILED BEFORE BUT GRANTED AFTER AN IMPROVEMENT PATENT.

In holding that Lilly's basic patent is invalid for obviousness-type double patenting, the Federal Circuit has rendered a decision that is directly in conflict with the established rule, which is:

> When a basic patent is filed before but issued after an improvement patent, the order of issuance is disregarded and the later-issuing basic patent is upheld if the improvement patent is not obvious in light of the basic patent.

See 3 D. Chisum, *Patents*, § 9.03 [2][c] (2001) and precedents cited therein. The rule applies when the basic invention was available as prior art against the improvement invention and when it was not.[3] From the leading case of *Thomson-Houston Electric Co. v. Ohio Brass*[4] in 1897 until the Federal Circuit decision of May 30, 2001, we are unaware of any court invalidating an earlier-filed but later-issued basic patent for double patenting when the improvement patent was not obvious in light of the basic patent, in the absence of inexcusable delay.

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[3] In the present case the basic patent was available as prior art under 35 U.S.C. § 102(b) and § 103 with respect to the improvement patent because Lilly was granted an earlier patent on an application having the same disclosure as the basic patent. The precedent established by the Federal Circuit's decision, however, also will harm owners of basic patents that were not available as § 102(b) and § 103 prior art.

[4] 80 F. 712 (6th Cir. 1897) (William Howard Taft, J.)

The circumstances of the present case are dramatically different from those of *In re Berg*,[5] relied on by the Federal Circuit, where the basic and improvement applications were filed on the same day and the inventions were made "at nearly the same time" and could have been included in the same application. Lilly could not have included the basic and improvement inventions in the same application because the applications had no inventors in common and the inventions were not made at the same time. The application for the improvement patent was filed 9 years after the application for the basic patent.

The Federal Circuit's rule of invalidating the earlier-filed but later-issued basic patent if it is obvious in light of the improvement patent, in the words of Judge William Howard Taft in the *Ohio Brass* opinion, "would be a hard one; and . . . we should be inclined, if possible, to avoid declaring it to exist."[6] Claims for a basic invention always or almost always will be obvious in light of the improvement invention.

The opinion below failed to identify delay in prosecuting Lilly's basic patent that would be unreasonable or unjustifiable.[7] As observed by Judge Taft in *Ohio Brass*, ". . . the course of an application for a generic or broad invention may legitimately take longer in its course through the patent office than a comparatively unimportant improvement on that invention."[8] Footnote 7 of the opinion below adopts a nearly impossible-to-meet standard—that the U.S. Patent & Trademark Office must have been "solely" responsible for the delay—citing an expert who said "the claim could have been presented earlier." A claim granted

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[5] 140 F. 3d 1428, 46 USPQ 2d 1226 (Fed. Cir. 1998).

[6] 80 F. at 724.

[7] IPO has no position on whether delay in fact occurred that was unreasonable or unjustifiable.

[8] 80 F at 724.

in a basic patent generally could have been presented earlier. Moreover, it is very difficult for companies with significant patent portfolios to keep track of the status of basic and improvement patent applications in the Patent and Trademark Office. A patent owner should not be penalized for late issuance of a basic patent unless there was prosecution laches.[9]

II. THE FEDERAL CIRCUIT'S DECISION WILL DISCOURAGE INVENTORS FROM APPLYING FOR BASIC AND IMPROVEMENT PATENTS

The decision below establishes a precedent harmful to the patent system and the members of IPO. It denies innovators the full patent life to which they are entitled for their basic patents. The decision penalizes the basic innovator, who is the person most likely to make improvements in the basic invention but who now will be deterred from filing for patents on improvements. The prospect of losing patent term will discourage innovators from using the patent system and will weaken the patent system's incentives for innovation, investment and, commercialization.

The unfairness of the Federal Circuit's decision is highlighted by the fact that the full term of the basic patent would be available if the improvement patent were owned by anyone other than Lilly. Judge Taft's analysis in *Ohio Brass* was as follows:

> According to the argument of counsel, the patentees of the earlier improvement patent and the later main patent being the same person, the main patent is void. Let us suppose that they were different persons, but that, by

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[9] Cf. Webster Electric Co. v. Splitdorf Electrical Co. 264 U.S. 463 (1924); Brief of *Amicus Curiae* Intellectual Property Owners Association, *Symbol Technologies Inc. v. Lemelson Foundation, Limited Partnership* 00-1583 (Fed. Cir. 2000).

> mean assignments, the two patents became the property of one person; the effect upon the public use of the improvement patent is exactly the same as if the new owner had been the inventor and patentee of both. Does the unity of title avoid [sic: void] the main patent, which was valid before? It must be so if the argument of counsel for defendant on his behalf is to be followed, for the effect of the unity of title is "to extend the monopoly" of the earlier improvement patent in the sense in which the counsel uses that phrase. To our minds, this conclusion is reductio ad absurdum.[10]

III. THE FEDERAL CIRCUIT MISAPPREHENDED THE LAW GOVERNING DISCLAIMERS OF THE TERMINAL PORTION OF A PATENT TO OVERCOME AN OBVIOUS-TYPE DOUBLE PATENTING REJECTION.

The opinion below has created new law governing the use of a terminal disclaimer to overcome an obviousness-type double patenting rejection. Footnote 5 in the opinion states:

> A patent owner cannot avoid double patenting by disclaiming the earlier patent. Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. . . .

We are aware of no precedent or rationale for a rule that a first-issued patent must still be in effect in order for the terminal portion of a second patent to be disclaimed. The Federal Circuit cites no authority for such a rule, and 35 U.S.C. § 253 provides no support. The opinion could open the door to arguments that no opportunity to file a terminal disclaimer is available in various circumstances. For example,

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[10] 80 F. at 727.

would a terminal disclaimer be available to overcome a double patenting rejection against a second patent after the first patent had lapsed for failure to pay a maintenance fee? Would a terminal disclaimer be available to overcome a double patenting rejection if the first patent had been declared invalid for reasons not affecting the second patent? IPO is concerned that the Federal Circuit's decision will create confusion in the law to the detriment of its members.

CONCLUSION

IPO believes the Federal Circuit misapprehended well-established precedent regarding obviousness-type double patenting. Accordingly, IPO urges this Court to grant the Petition for Writ of Certiorari.

Respectfully submitted,

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APPENDIX

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No. 01-660

Supreme Court, U.S.
FILED
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In The

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC.,
AND
APOTEX, INC. and BERNARD C. SHERMAN,
AND
GENEVA PHARMACEUTICALS, INC.,
AND
INTERPHARM, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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REPLY BRIEF

The rule of law announced by the Federal Circuit effectively requires a patentee to forfeit an *entire basic patent*, not just any "unjustified" extended period of exclusivity, for no other reason, and based on no other facts, than that the Patent and Trademark Office ("PTO") issued that patent after the PTO had issued a separate patent on a concededly *nonobvious*, patentably distinct, follow-on invention. This facially illogical rule does violence to the statutory scheme and will have profoundly adverse consequences not just for untold numbers of basic patents in "reverse order of issuance" cases, but for the patent system as a whole, as Lilly's amici emphasize.

1.a. Barr does not dispute that Lilly's application to patent its improvement invention (Stark) referred explicitly to its earlier-discovered basic invention (Molloy) as "prior art." Nor does Barr contest that Stark was correctly found by the PTO to be a nonobvious improvement over Molloy, and that Section 103 therefore provides that the two inventions are "patentably distinct." As Barr acknowledges, not a single case in the century-old, 500-plus-case jurisprudence on obviousness-type double patenting has ever applied the nonstatutory doctrine to invalidate a "prior art" basic invention in light of a later-discovered, later-filed, nonobvious improvement invention. Barr Brief in Opposition ("Barr Opp.") at 1, 11-13.[1]

For this reason, and because the only common-sense way to test "obviousness" is to ask whether the *later* discovered and filed invention is nonobvious in light of the *earlier* discovered and filed invention, Lilly submits that its Stark and Molloy patents cannot, as a matter of law, be held to be "double patents." As Judge Newman aptly put it in dissent below, "[w]hatever effect the '549

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[1] Barr's citation of *In re Borg*, 392 F.2d 642 (C.C.P.A. 1968), is inapposite because it held that a later-filed invention (Borg) was "double patenting" in light of an earlier-filed invention (Zajac) that the PTO had *not* applied as prior art.

[Molloy] and Stark patents may have on each other, it is not 'double patenting.' " Pet. App. 43a.

Because it cannot deny that the Molloy and Stark inventions are patentably distinct under Section 103, Barr argues that "Section 103 determines whether the claimed invention is patentable over the statutory prior art," whereas "[t]he double patenting doctrine . . . determines whether the applicant is improperly extending its patent monopoly beyond the statutorily-prescribed term." Barr Opp. at 17. But this facile description is entirely circular. The judicial "double patenting" doctrine will find a patent monopoly extension to be "improper" *only* where it finds that two patents have issued for patentably *indistinct* inventions. Thus, the Federal Circuit has repeatedly stated that " 'as a matter of law the extension of protection objection is not necessarily controlling.' "[2]

In short, what matters in double patenting is not whether one patent's term extends beyond that of another, but whether the two patents cover patentably indistinct inventions. Here, because the Molloy and Stark inventions have a prior art relationship, the PTO correctly applied Section 103 and determined that the inventions are patentably distinct, and it therefore makes no sense to apply any additional, nonstatutory test of patentable distinctness.[3] And given that there is no finding, evidence,

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[2] *See In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991) (citing *In re Borah*, 354 F.2d 1009, 1017 (C.C.P.A. 1966); *In re Stanley*, 214 F.2d 151 (C.C.P.A. 1954)).

[3] By contrast, for commonly owned inventions that do *not* have a prior art relationship, the judicial doctrine of double patenting (rather than Section 103) serves to determine patentable distinctness. *See* Pet. at 17-21. Contrary to Barr's claim, Barr Opp. at 16, *In re Bowers*, 359 F.2d 886 (C.C.P.A. 1966), actually confirms that the two tests are "mutually exclusive," whereby Section 103 determines patentable distinctness for earlier inventions that are in the statutory "prior art," and judicial double patenting does so for that subset of earlier or

or even *allegation* in the record of this case that " 'the delay in the issuing of the patent for the main [Molloy] invention [can] be charged to the laches or fraud of the patentee,' " Pet. at 22 (quoting *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. at 712, 724 (6th Cir. 1897) (Taft, J.)), both the Molloy and Stark inventions are entitled to separate patents with independent patent terms.

b. Nevertheless, even if the nonstatutory doctrine of obviousness-type double patenting applied here, it would hold that "the order of issuance should be disregarded in this special situation and the later issuing [basic] patent should be upheld if the improvement is patentably distinct from the [basic] invention." CHISUM ON PATENTS § 9.03[2][c] (2000) (citing cases). Double patenting cases, including those cited by Barr, focus on inventions made at around the same time, for which patents were sought contemporaneously, but in different applications. Barr Opp. at 17-19. In that context, they inquire whether the invention claimed in the *later-issued* patent is nonobvious in light of the invention claimed in the *earlier-issued* patent.

But as even Barr acknowledges, this inquiry is reversed " 'to prevent rejections for obviousness-type double patenting *when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing.*' " Barr Opp. at 19 (citing *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998)) (emphasis added). This common-sense approach, the so-called "two-way test" for double patenting, adheres to the patents' "order of discovery," examining whether the later-discovered improvement invention is nonobvious in light of the earlier-discovered basic invention, notwithstanding the fact that the patents on those inventions were issued by the PTO in reverse order of their filing. Thus, a Federal Circuit decision cited by Barr as an example of the two-

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contemporaneous inventions that are statutorily *carved out* of the prior art. *See* 359 F.2d at 889.

way test for double patenting holds that "when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention." *In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991). Under that rule of law, Lilly clearly prevails in this case.

According to Barr and the Federal Circuit, however, this common-sense "two-way" test applies only when the PTO was "solely responsible" for the delay that caused the patent on the later-filed improvement invention to issue before the patent on the earlier, basic invention. Pet. App. 24a n.7; Barr Opp. at 19-21. And here the Federal Circuit determined that the PTO was not "solely responsible" for the issuance of the Stark improvement patent before the Molloy basic patent only because Lilly's claims on the basic invention "could have been presented earlier." Pet. App. 24a-25a n.7.

But, as Lilly's amici demonstrate, it will always, or virtually always, be possible to say that the claims in a basic patent "could have been presented earlier." Brief of Amicus Intellectual Prop. Owners Ass'n ("IPO Br.") at 5-6; Brief of Amicus Biotechnology Indus. Org. & Pharm. Research Mfrs. ("BIO Br.") at 13, 15. For example, while Lilly complied with all filing deadlines in prosecuting its Molloy claims, it certainly could have made some filings earlier. For the Federal Circuit now to require Lilly to forfeit entirely its valuable Molloy patent because its claims "could have been presented earlier" is akin to denying a petition for certiorari filed on the 90th day – while it was not untimely, it "could have been filed earlier." Indeed, no matter how blameworthy the PTO may be in a given case for the reverse order of issuance of basic and improvement patents, it will rarely if ever be *solely* responsible, since the patent holder could have taken some action "earlier." Thus, the Federal Circuit has announced a radical new standard that will inevitably result in the *a priori* denial of the full patent term for

otherwise patentable basic inventions in all "reverse order" cases. *See* IPO Br. at 5-6; BIO Br. at 13.

In sum, whether it erred in applying the nonstatutory double patenting test to two inventions found to be patentably distinct under Section 103, or in refusing to honor the common-sense principles behind the two-way test exception, the Federal Circuit held that Lilly's patent on its basic Molloy invention must be forfeited in its entirety based solely on the fact that it issued seven months after a patent on the nonobvious Stark improvement invention, and on the inevitable reality that the Molloy claims "could have been presented earlier." No other facts were thought to be relevant to the decision to invalidate Lilly's basic Prozac patent. However the rule of law from this decision is described, it is plainly wrong and demands review by this Court.

c. In an effort to provide an *ex post* justification for the Federal Circuit's harsh decision, Barr repeatedly asserts that Lilly "intentionally" and "strategically" delayed issuance of its basic Molloy patent. *See, e.g.*, Barr Opp. at 2-7, 12, 21, 23.

First, Barr's gravely serious charges are conspicuously lacking in supporting citations to the evidentiary record in this case. This is not surprising, given that there is no evidentiary record on Barr's charges. After all, the district court granted *summary judgment* for Lilly on Barr's double patenting defense, and Barr never even alleged, let alone proved, that Lilly had intentionally delayed the progress of its Molloy application or had otherwise engaged in dilatory conduct or prosecutorial laches. To the contrary, Lilly applied for a patent on its basic discovery in 1974, but did not obtain its Molloy patent in direct response to that application largely because *the PTO* determined that Lilly's initial application contained multiple innovations, and therefore was *required* to be broken up into multiple "divisional" applications. That decision by the PTO, not any action taken by Lilly, launched Lilly on a highly complicated, contentious 12-year application process, resulting in multiple

"basic" patents covering different aspects of its initial Prozac innovation. Pet. at 7-8.

Indeed, there was nothing whatsoever dilatory about Lilly's prosecution of the Molloy patent. Lilly conformed in *every* respect with *all* of the procedural requirements that governed the prosecution of its patents, including those governing timeliness,[4] and there has never been any claim to the contrary. Thus, Barr explains, "[t]he PTO promptly issued" the Molloy patent in 1986 in full view of Lilly's other related Prozac patents, yet it voiced no qualms about the 12-year period since Lilly's initial 1974 application. Nor did the district court raise a question about Lilly's good faith in prosecuting its Molloy patent.

Second, Barr does not and cannot contest the fact that the prosecution of patents relating to a pathbreaking innovation like Prozac will often last for a decade or more. Indeed, it makes no effort to distinguish cases with similar prosecution histories that were found to be wholly unproblematic. *See* Pet. at 8 nn.1-3. The patented claims at issue in those cases surely "could have been presented earlier," yet that was hardly a sufficient basis for invalidating those patents.

Finally, Barr fails to explain how Lilly's alleged "manipulation" of the issuance of its basic Molloy patent has any legal relevance to this case. The decision below is predicated on the existence of the Stark patent, which has never had any commercial value to Lilly and was disclaimed in its entirety during the pendency of this case. *See* Pet. at 10. Indeed, Lilly would have enjoyed precisely the same benefit of the alleged "strategic delay" had it never obtained the Stark patent. Thus, the decision below cannot intelligibly be attributed to any alleged "strategic delay."

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[4] *See, e.g.*, 35 U.S.C. § 120; *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968).

2. Barr and Respondent Geneva Pharmaceuticals, Inc., understandably refuse to defend the manifestly irrational reasoning that because Lilly had previously disclaimed the Stark patent in its entirety it cannot now terminally disclaim Molloy. *See* Pet. App. 23a; Pet. at 27-30. Rather, Respondents argue that "[i]t is simply too late" for Lilly even to raise the issue of its right under Section 253 to terminally disclaim Molloy. Barr Opp. at 7; Geneva Brief in Opposition ("Geneva Opp.") at 1. At the root of this argument is the fact that Respondents "argued for six years that the [Molloy] patent was invalid for double patenting and during that whole time, Lilly never filed a terminal disclaimer." Barr Opp. at 25; *see* Geneva Opp. at 2-3. Thus, Respondents contend that when they raised their double patenting defense to Lilly's infringement claim, Lilly was put to an election: either Lilly could file a terminal disclaimer then and there (and thus surrender on the merits of the double patenting defense) or it could dispute the merits of the double patenting defense (and thus waive its statutory right to later terminally disclaim any portion of the Molloy patent found to constitute an unjustified timewise extension).

Respondents' contention is absurd on its face. Nothing in the language of Section 253, or in logic, precludes a post-judgment terminal disclaimer or otherwise places such a purposeless temporal constraint on a patent holder's critically important right to "*overcome a rejection* based on double patenting." *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) (emphasis added). To the contrary, the language of both the statute and the cases applying it makes clear that a patent holder need not terminally disclaim his valuable patent rights until his patent has been rejected or invalidated for double patenting. *See, e.g., Quad Envtl. Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("In legal principle, the filing of a terminal disclaimer simply serves the statutory function of *removing the rejection of double patenting* . . . . ") (emphasis added); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("patentee may *overcome* the double patenting

rejection by filing a terminal disclaimer"). Not surprisingly, neither Barr nor Geneva offers a single case supporting their reading of the statute.

Indeed, the decision below itself refutes Respondents' contention. The court said nothing at all about timeliness, and its ruling necessarily implied that Lilly *would* have been able to terminally disclaim Molloy *if* it had not previously disclaimed all of Stark. As Lilly's amici stress, the Federal Circuit's ruling on Section 253 has sweeping implications and is independently worthy of this Courts' review. IPO Br. at 7-8.[5]

3. In an effort to support its claim that this case is not "important," Barr erroneously states that Lilly argued in the court below that the issue in this case had never before arisen. To the contrary, Lilly argued below, as here, that no court has ever invalidated a basic "prior art" patent as obvious in light of a later-discovered, later-filed, but earlier-issued patent on a patentably distinct improvement invention. Thus, this case is unprecedented only because of the radical *rule of law* it announces, not because of the commonplace facts it addresses.

Noting that the patent law was amended in 1995 to measure a patent term not as 17 years from the date of

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[5] As anticipated, Pet. at 28 n.10, Respondents labor mightily to mislead this Court into the false belief that the Federal Circuit's *actual* decision preemptively truncating Lilly's (and countless others') enormously valuable terminal disclaimer rights under Section 253 somehow should not concern this Court because Respondents made another double patenting argument below (relating to Lilly's "Holland" patent for hypertension) that, *if* it had been accepted by the Federal Circuit, would not have given rise to any terminal disclaimer issue. But the Federal Circuit carefully and deliberately did *not* accept Respondents' Holland-based double patenting argument, and the Stark-based double patenting argument that the Federal Circuit *actually did* accept *actually did* give rise to the Court of Appeals' profoundly important, clearly wrong, and plainly certworthy terminal disclaimer ruling.

issuance, but rather as 20 years from the date of application, 35 U.S.C. § 154, Barr argues that it is "exceedingly unlikely" that the issue in this case will ever arise again. Barr Opp. at 13-14. It is true that the 1995 rule addresses the problem of "inordinate delays in the PTO," so that doctrines such as laches and inequitable conduct will likely be invoked less frequently. But this is not a laches case. This is a double patenting case, and the 1995 rule change has *nothing* at all to do with the determination of when two inventions are patentably distinct versus when there is "double patenting."

Nothing in the 1995 law obviated the need to determine whether two inventions are patentably distinct. Thus, as Lilly's amici emphasize, the Federal Circuit's decision will "effectively lead to a *per se* rule" in all future cases involving "reverse order of issuance," resulting in "the inappropriate invalidation of claims in distinct patents that *each* fully meet the requirements for patentability." BIO Br. at 16. This expansive *per se* rule will produce a number of harsh results that are wholly unaffected by the 1995 rule change.

First, the decision below will still invalidate the terminal portion of any basic patent that expires after a nonobvious improvement patent, even if the later expiration of the basic patent's term has nothing at all to do with laches or inexcusable delay on the part of the patentee.[6] Second, just as Lilly has lost its Molloy basic

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[6] The phenomenon of a basic patent lawfully expiring later than the patent on a later-discovered, nonobvious improvement invention will still exist for patents covered by the 1995 rule. For example, it will certainly be possible under the law for a patentee to apply for his basic patent up to twelve months after he applies for his improvement (and after he publicly discloses his basic invention as prior art to that improvement). In addition, under a 1999 amendment a basic patent may be given an extension on the normal 20-year term wherever, as in this case, the PTO has contributed to the delay in issuing that patent. See BIO Br. at 17 n.11.

patent even for that period during which Molloy merely overlaps Stark's term, the decision will require any "double patent" that has a disclaimed or disowned "twin" to be *completely invalidated* even though it presents no issue of "timewise extension" whatsoever. Third, the Federal Circuit's decision will require a finding of double patenting with respect to post-1995 basic patents in "reverse order of issuance" cases even if the basic invention's patent term will expire *before* that of the later-discovered, nonobvious improvement; the patentee will thus be precluded from selling or transferring either of its "double patents," thereby substantially reducing their commercial value. 37 C.F.R. § 1.321(c)(3) (2001).

Finally, of course, there are untold numbers of pre-1995 patents that will fall under the Federal Circuit's radical new theory of obviousness-type double patenting. That prospect alone will profoundly alter the landscape of patent-dependent, high-technology industries in this country for at least a decade to come. BIO Br. at 18-19.

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Supreme Court, U.S.
FILED
DEC 13 2001
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No. 01-660

In The

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ELI LILLY AND COMPANY.,

Petitioner,

v.

BARR LABORATORIES, INC.,
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GENEVA PHARMACEUTICALS, INC.,
and
INTERPHARM, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF RESPONDENT GENEVA PHARMACEUTICALS, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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RESTATEMENT OF LILLY'S SECOND QUESTION PRESENTED

2. Did the District Court err by recognizing that Lilly could not resurrect a patent previously ruled invalid by filing a post-judgment terminal disclaimer, particularly where the terminal disclaimer, to be effective, must disclaim that portion of the patent term that extends beyond October 31, 2000, i.e., thus leaving no remaining patent term to resurrect?

PARTIES AND CORPORATE DISCLOSURE

There are no named parties other than those stated in the caption. Respondent Geneva Pharmaceuticals, Inc. is a wholly-owned subsidiary, through intervening wholly-owned subsidiaries, of Novartis AG.

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BRIEF IN OPPOSITION

In this brief in opposition to Eli Lilly Company's ("Lilly") petition for a writ of certiorari, respondent Geneva Pharmaceuticals, Inc. ("Geneva") will address only Lilly's second question presented for review, i.e., whether Lilly should be able to resurrect the '549 patent by filing a terminal disclaimer? As to the first question presented, whether the '549 patent is invalid for double patenting, respondent Barr Laboratories, Inc. ("Barr") has pointed out why Lilly's petition should be denied, and further comment by Geneva is unnecessary.

Even as to the second question, Barr correctly notes that Lilly's post-judgment offer to file a terminal disclaimer simply comes too late. Lilly's terminal disclaimer offer, and accompanying argument, is made for the first time in this Court, and for that reason alone renders the grant of Lilly's petition inappropriate.

That, however, may not entirely end the matter. Supreme Court Rule 15.2 admonishes counsel for respondent(s) "that they have an obligation to the Court to point out in the brief in opposition, and not later, any perceived misstatement [of fact or law] made in the petition."

Although the Barr opposition easily complies with Rule 15, particularly in noting (which Lilly's petition did not) that Lilly's terminal disclaimer offer and argument are presented for the first time in its petition, Geneva nevertheless believes that this Court is entitled to a detailed explanation of the underlying facts.

As will be explained below, not only is Lilly's second question presented untimely, but is so factually flawed as

to reflect adversely on the credibility of Lilly's entire petition.

Lilly's silence as to the timing of its fallback argument cannot shield it from further inquiry. At the very least, this Court is entitled to know *why* Lilly did not offer, before October 16, 2001 (when it filed its petition for a writ of certiorari), to disclaim any portion of the now-invalid '549 patent.

Lilly's Assertion that the "Federal Circuit Erred in Pre-Emptively Denying Lilly the Statutory Right to Terminally Disclaim the Molloy Patent" Is Disingenuous

Lilly ill-serves its cause when it asserts, as its fallback argument, that the Federal Circuit improperly denied Lilly the opportunity to "terminally disclaim" only that portion of the later-expiring '549 patent that extends beyond the expiration of the earlier-expiring Stark patent – i.e., the last seven months of the '549 patent. By this simple expedient, says Lilly, it should be able to recoup all but seven months of the 26 years of patent protection that Lilly had hoped to enjoy for its Prozac® product.

As noted in Barr's response, during the entire course of this lawsuit, including the briefing in the district court, the briefing on appeal leading up to the August 9, 2000, panel holding of invalidity for double patenting, the briefing on Lilly's petition for rehearing leading up to the May 15, 2001, revised panel holding, and the briefing on Lilly's second petition for rehearing, *never once* did Lilly come forward and offer to disclaim any portion of the '549 patent term "to preserve the validity of the Molloy

['549] patent." (Petition at 28). That Lilly fails even to acknowledge the lateness of its argument, much less explain it away, renders Lilly's argument unworthy of Supreme Court review.

Surely this could not have been an oversight. As correctly noted by Lilly, "[i]t is well-established that a common assignee is entitled to proceed with a terminal disclaimer to overcome a rejection based on double patenting of the obviousness type." (*Id.* at 27). If not an oversight, what actually did happen?

The answer is quite simple. In late 1997, Barr discovered that Lilly had issued to it *two* non-Molloy patents that claimed specific uses of fluoxetine. One was the Stark patent relied upon by the Federal Circuit in its second holding of invalidity. The other was U.S. Patent No. 4,329,356 to Holland. Stark, which had an expiration date of May 20, 2003, claimed the use of fluoxetine to treat anxiety. Holland, which had an even earlier expiration date of October 31, 2000, claimed the use of fluoxetine to treat hypertension.[1]

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[1] Claim 1 of Stark reads as follows:

1. A method for treating anxiety in a human subject in need of such treatment which comprises the administration of said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically acceptable salts thereof.

Claim 13 of Holland reads as follows:

13. A method for lowering blood pressure in hypertensive mammals in need of treatment which comprises the administration to such a mammal of an antihypertensive amount of fluoxetine or a pharmaceutically-acceptable salt thereof.

Immediately upon learning of these patents, both of which had expiration dates prior to the '549 patent, Barr notified Lilly that the '549 patent was invalid for double patenting based on either or both of Stark and Holland. In sharp contrast to its present last-ditch complaint that it should have been allowed to file a terminal disclaimer as to the last seven months of the '549 patent term, Lilly did not offer (even on a contingent basis) to disclaim any part of the '549 patent.

Instead it disclaimed the earlier-expiring Stark and Holland patents.

From that day forward, up to and through the Federal Circuit's May 15, 2001 panel decision, Barr consistently and strenuously argued that Lilly had disclaimed the wrong patents. Only by disclaiming the *later-issued* and *later-expiring* '549 patent could Lilly obviate the unlawful patent extension it had obtained by means of the '549 patent.

Not only did Lilly refuse to disclaim any part of the '549 patent, but its refusal was calculated and intentional, and indeed was borne of dire necessity.

The reason was that Lilly knew full well that if it were to terminally disclaim the '549 patent, this terminal disclaimer would have to date from the earliest expiration date of Stark *or* Holland. While Stark would expire on May 20, 2003 (a mere seven months prior to '549), Holland was to expire on October 31, 2000, i.e., over three years prior to the '549 patent's December, 2003 expiration. A terminal disclaimer of the '549 patent effective as of October 31, 2000, would have mooted this case as to

the '549 patent, since such a disclaimer would have provided Barr with all of the relief that it could have possibly obtained as to that patent – namely, its removal as a barrier to the launch of Barr's generic fluoxetine product on August 2, 2001 (when yet another of Lilly's fluoxetine patents expired). Lilly concedes as much in its petition, noting that if Holland had been relied upon by the Federal Circuit, a terminal disclaimer would have ended the inquiry, "because, unlike Stark, the Holland patent is now expired." (*Id.* at 28, n.10).

In a tacit admission that its double patenting problems did not reside solely with Stark, Lilly seeks, by way of the same footnote, to distinguish between Stark and Holland as a basis for a double patenting holding. According to Lilly, Holland "cannot support a double patenting holding . . . [because] it deals with peripheral effects of fluoxetine outside the brain and cannot, therefore, be linked to blockage of serotonin uptake in brain neurons as claimed in the Molloy patent." This Court will search the record in vain for any such argument in the courts below. Throughout this case, the double patenting issue as it related to Stark was briefed in conjunction and identically with Holland. They were addressed as a pair, with every argument and response applied equally to each.[2] Both patents claimed specific uses of fluox-

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[2] *See*, for example, Opening Brief of Appellant Barr Laboratories, Inc., heading at 38: "Lilly's Disclaimer Of The '356 [Holland] And '213 [Stark] Patents Cannot 'Undo' Its Double Patenting Violation." In Lilly's Brief, under the heading "Facts Relating to the Defense Based on the Holland and Stark Patents," Lilly argued that Holland and Stark present "virtually the identical situation" (Brief at 24). Lilly then proceeded to

etine; Stark to treat anxiety, Holland to treat hypertension.

Indeed, in the courts below, not only did Lilly fail to distinguish between Stark and Holland,[3] it offered the same basic argument with respect to both – namely, that by disclaiming Stark and Holland as soon as Barr cited them to Lilly as a basis for its double patenting defense, those patents became a nullity *nunc pro nunc*, and thus were entitled to the fiction that they never existed. Of course, and as noted above, Barr readily pointed out that Lilly had disclaimed the wrong patents, and that the only way to avoid the improper extension of the patent monopolies obtained and enjoyed by Lilly based upon Holland and Stark was to terminally disclaim that portion of the *'549 patent* that extended beyond the earliest expiration of Stark or Holland.

This is a matter of simple math and logic. Prior to the issuance of the '549 patent, Lilly had already enjoyed seven months of protection offered by Stark, and over *four years* of protection offered by Holland. Lilly went so far as to list these patents in the FDA "Orange Book," thereby effectively preventing third parties from obtaining FDA approval for the specific uses of fluoxetine claimed by Stark and Holland (i.e., to treat anxiety and hypertension, respectively). Since it was the *initial* terms

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offer five arguments, each with a caption that included "Holland and Stark" together. (*Id.* at 62-72).

[3] The Federal Circuit's reliance on Stark alone, rather than Holland or Holland/Stark was a matter of choice, judicial economy and restraint, it being unnecessary to set out a double basis for double patenting.

of Stark and Holland, when tacked on to the *full* later term of the patentably indistinct '549 patent, that resulted in the improper patent term extensions of Stark and/or Holland, the disclaimer by Lilly of the *terminal* portions of Stark and Holland was futile.

In fact, the Federal Circuit finding of which Lilly so bitterly complains (i.e., denying Lilly the right to terminally disclaim the '549 patent) was made in direct response to Lilly's then-argument that the disclaimer of Stark and Holland (but not the '549 patent) obviated the double patenting problem. The Federal Circuit expressly noted that the disclaimer by Lilly of Stark (and by extension Holland) aided Lilly not at all. As stated by the Federal Circuit, "[a] patent owner cannot avoid double patenting by disclaiming an earlier patent" (i.e., as Lilly tried to do by disclaiming Stark and Holland, both of which were "earlier" than the '549 patent). (Lilly petition, at 23a). The Federal Circuit's follow-on comment – i.e., that

> Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term, or as in this case, is the date it is terminated via disclaimer

– was not in response to any argument or offer made by Lilly. Rather, it was merely an observation that Lilly's ill-conceived disclaimer of Stark and Holland not only failed

to avoid double patenting, but that by its disclaimer of the wrong patents Lilly actually shot itself in the foot by putting in place an even *earlier* expiration date for Stark and Holland beyond which the '549 patent could not legally extend. Whether the terminal disclaimer of the '549 patent must be measured from 1977, when Lilly disclaimed Stark and Holland (as held to be the case by the Federal Circuit), or from October 31, 2000, when Holland would have expired if it had not been disclaimed, is of no moment. All that matters is that both deadlines have long since expired, and that Lilly's belated effort to disclaim only the last seven months of the '549 patent cannot right what the Federal Circuit properly held to be a fundamental wrong.

Moreover, Lilly's new-found and record-devoid argument that Holland "deals with peripheral effects of fluoxetine outside the brain" misses the point entirely. The Federal Circuit's holding that the claims of the '549 patent were not patentably distinct from the claims of the earlier-expiring Stark patent was based upon the unassailable fact (not here challenged by Lilly) that the '549 patent claims nothing more than the natural and inherent effect of fluoxetine when it is administered "for any purpose." As stated by the Federal Circuit,

> the limitation of claim 7 of the '549 patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride *for any purpose, including* the treatment of anxiety.

(Lilly petition, at 29a; emphasis added).

Had Lilly chosen to urge below that the treatment of hypertension with fluoxetine hydrochloride (as claimed by Holland) may be attributable to some biological effect other than blocking serotonin uptake, *which it did not*,[4] the above-quoted finding would have been dispositive. Simply stated, it does not matter how fluoxetine works in the body to ameliorate the various maladies for which Lilly and others have obtained patents; all that matters is that the later-expiring '549 patent claims nothing more than the inherent biological effect of fluoxetine when it is administered "for any purpose." A later patent that does no more than claim such an inherent effect is not patentably distinct from an earlier patent directed to a specific use of fluoxetine. As further held by the Federal Circuit,

> That is, fluoxetine hydrochloride inherently blocks serotonin uptake upon administration. Therefore, no patentable distinction rests between administrating fluoxetine hydrochloride for treatment of anxiety and inhibition of serotonin uptake by administration of fluoxetine hydrochloride.

(*Id.* at 30a).

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[4] Lilly's conscious failure to argue in the courts below that Holland and Stark presented different double patenting issues is further explained by the fact that Holland, on its face, acknowledges that the "chief pharmaceutical activity of fluoxetine is as a specific inhibitor of the serotonin pump." So too does Stark: "[fluoxetine] has been found to block the uptake of . . . serotonin." As noted by the Federal Circuit, it is this serotonin uptake blocking effect that is "an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose." (Lilly petition, at 29a).

To its credit, the Federal Circuit took special pains to explain this most basic of concepts. Citing the dissenting opinion of Judge Lourie in *Barroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994), the Court pointed out that

> allowing a common owner to receive both a patent claiming the physical act of treating individuals . . . and a patent covering the result that such treatment accomplishes makes "no sense" . . . It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain relieving mechanism by means of that treatment is another.

(*Id.*).

Far from pre-emptively denying Lilly anything to which it was lawfully entitled, the Federal Circuit provided in advance the complete answer to the argument that Lilly now submits for the first time in this Court.

CONCLUSION

Even if Lilly were now permitted to terminally disclaim the '549 patent, such a disclaimer would have to be effective as of October 31, 2000. Such a disclaimer would have mooted Lilly's appeal in the Federal Circuit, and will moot Lilly's present petition. Lilly knew this when it decided in 1997 not to disclaim or even offer to disclaim the '549 patent; Lilly knows it now.

To the extent Lilly's untimely second question presented is entitled to any weight at all in this Court, it is solely in connection with Lilly's credibility and hence

entitlement to relief of any kind. By its apparent decision that it had nothing to lose by advancing its terminal disclaimer argument for the first time in this Court, Lilly comes very close to admitting that its entire petition is without merit.

Respectfully submitted,

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